AN INVESTIGATION OF CLINICAL TRIAL MANAGEMENT FROM AN RESEARCH ADMINISTRATORS PERSPECTIVE; A GUIDE FOR THE EARLY STAGES OF CLINICAL TRIAL MANAGEMENT WITHIN THE JOHNS HOPKINS UNIVERSITY DEPARTMENT OF MEDICINE

by
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Abstract

Clinical trial research is performed across the world and is an important component of research administration. The complexity of clinical trials highlights the importance of the initial stages of clinical trial set up within an institution. Without a proper process, lengthy agreement and contract negotiations get drawn out even further, and poor document management leads to extensive delays in getting appropriate information to the institution, sponsor, and research group. While policies and procedures are available within Johns Hopkins, the way in which clinical trials are managed within the Department of Medicine is reliant upon individuals working on trials in their respective divisions. This means, analysts and researchers must rely on word of mouth, and co-workers as to who they contact to get their clinical trial up and running. This researcher surveyed anonymous individuals within the research administration field to assess if the clinical support issues run into by the researcher was a common issue amongst others in the field of clinical trial management. While the number of participants was much less than expected, the results echoed the researcher's hypothesis, in that the need for internal clinical trial management guides is dire. In question 5 of the survey, participants were asked "Does your institution provide clear policy and management structure guidelines regarding clinical trial management?"; 90% of participants answered no (Best, 2020).

The results from the survey, literature review, and personal experience of the researcher, were then utilized to develop the Department of Medicine Initial Clinical Trial Management Guide within Appendix A. While there are many steps within the clinical trial management process, the researcher focused on the first step in getting a clinical trial initiated within an institution. The guide provides users with definitions, essential departmental contact information, checklists, forms, and email templates, to guide them through the initial steps of a clinical trial

initiated within the Johns Hopkins University Department of Medicine. Although much support is still needed to assist analysts in managing clinical trials, this guide fills a hole within the Johns Hopkins University Department of Medicine in the initial stages of clinical trial management. The official reader of this thesis is Jeffrey E. Kantor, Ph.D.

Dedication

This thesis is dedicated to my husband Royce. Thank you for your unending love and support.

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Introduction

Clinical trial management is a time consuming and critical activity in sponsored research. The pre to post award process of a clinical trial can take several months with a number of intricate details that must be negotiated, and agreed upon long before a clinical trial can begin. In addition to the difficulty in managing a clinical trial, the support and institutional management systems vary greatly causing additional issues and problems for all parties involved with a clinical trial. While many institutions have designated Clinical Trial Offices, many institutions do not, or have a variation of a Clinical Trial Office. The organizational structure in which a Clinical Trial Office is a centralized part of research institutions is one even the largest research institutions like Johns Hopkins have not solidified. This structural gap can and does have detrimental consequences to the retention and management of sponsored funds which could jeopardize current and potential funding opportunities.

Researchers within the Johns Hopkins University and Johns Hopkins Health systems are very much on their own in terms of clinical trial support regarding the management of clinical trials. Offices such as the Office of Research Administration, Sponsored Projects Shared Services, and Clinical Research Support Services, exist and are crucial to the support of clinical trial work flow and clinical trial management. Those offices, which are key to work flowing clinical trials through the appropriate JHU channels, are very much isolated in their own departments and work interpedently of departmental offices where the clinical trial research is performed. This meaning that researchers and clinical trial personnel must understand the intricate workings of those offices, and what those offices can provide in terms of research administration to their specific clinical trial or sponsored project support.

This thesis looks at the Clinical Trial Office structure that exist within some research institutions, identifies the common issues research administrators face regarding clinical trial management, and provides clinical trial management best practices that can be utilized by researchers or clinical trial personnel to better assist them in managing the initial stages of their clinical trial within their respective institutions. Based on this information, an initial clinical trial management guide for research administrators was developed.

Review of the Literature

The topic of clinical trial management has been discussed in the research community for many years. While topics such as types and sizes of trials has been discussed by the Farrell et. al article *Managing Clinical Trials*, specifics regarding how those trials should and could be managed has not been prevalent in those publications (Farrell, 2010). In the article titled "Managing Clinical Trials" by Farrell, et. al., the authors mention that 'randomized trials involves a huge investment of time, money and people; therefore, it warrants expert management and needs to be managed from its inception like any other business. Due to the extensive demands and finite details that are structured into trials, the lack of clinical trial management structure can and has caused trials to fail or research not to be explored to its full capacity. As Farrell et. al, points out, "clinical trial management is essential amongst the key competencies that are needed to deliver high-quality trials".

To ensure clinical trials are managed optimally, research institutions should incorporate systematic structures of support for clinical trial management. In a study done by the Association of Academic Health Centers, it was found that Clinical Trial Offices or CTOs have in recent years been incorporated into the academic health center research infrastructure as a way to consolidate administrative activities related to clinical trials, specifically from protocol

development to billing compliance (Rubin, Lazar, 2018). In 2008, the Association of Academic Health Centers chose to look at eight universities which incorporated a CTO in order to learn about the scope and operations of those offices within those institutions (Rubin, Lazar, 2018). As Rubin and Lazar point out in their article, each of the institutions that were chosen to review had varying approaches to the management of clinical trial research. While not leading readers regarding which CTO was the "correct" choice to be implemented across research institutions, the need for a CTO, and the structure a CTO provides in regards to managing clinical trial and sponsored projects was apparent in each of the eight institutions whose CTO were analyzed. When formal CTOs are not established in research institutions, personnel new to managing clinical trials must learn to navigate institutional policies involving clinical trials on their own. When support, which comes from an established CTO, is missing, communication between departments and institutional compliance offices is hindered, understanding regarding institutional compliance policies in respect to trials is missed, thus resulting in the failure to manage clinical trials in a timely and compliant way. If no CTOs are in place on an institutional level, small departments within those research institutions suffer significantly. The article by Rubin and Lazar (2018) points out, the current administrative landscape within research institutions is complex.

> Many interdependent functions are spread across the research enterprise, which often results in the establishment of administrative structures and small bureaucracies operating as separate, unconnected silos that lack policies or formal procedures for communications and interaction (Rubin, Lazar, 2018).

With institutions operating as individual entities within the institution as a whole, with no support or structure from a formal CTO office, smaller departments must create their own

policies to follow in managing clinical trials. In terms of clinical trial management, a couple smaller departments provide their clinical trial personnel with access to department created clinical trial management guides. The University of California, Davis Health (UC Davis Health) clinical trials office site offers their clinical trial personnel a Tools for Study Management website acting as a guide to assist new personnel in how clinical trial management. The site offers blank word and PDF templates personnel can copy and alter to meet their specific trial needs (UC Davis Health, 2020). The following categories offer blank documents to personnel to utilize and assist in their trial management: Protocol, Patient Management, Study Management Tools, Recruitment Tools (courtesy of Beth Harper, Clinical Performance Partners), Radiology Procedure Request Form, Pathology (Laboratory) Forms, Consent, Epic Certification for Part 11 Compliance, Disclosure Tracking Database, IT Evaluation Forms, UC Davis W-9, IDS Fee Form (2015) (UC Davis Health, 2020).

While the aforementioned categories provide a wealth of information, the Tools for Study Management site as a whole does not address which departments to contact specifically to submit trial data to initiate a trial, and how that data is tracked and reported in the UC Davis system. While boiler plate forms are necessary and extremely helpful, the procedural structure of how a trial is managed is missing from the UC Davis Health guide. In addition to UC Davis Health, the University of Pennsylvania Perelman School of Medicine Office of Clinical Research (OCR) Industry Sponsored Study Guide also provides personnel with a clinical trial management guide. Unlike UC Davis Health, the Perelman School of Medicine OCR Sponsored Study Guide provides personnel with a quick reference guide to 7 functional steps to "help Investigators and their team navigate clinical research from start-to-finish" (University of Pennsylvania Perelman

School of Medicine, 2020). Personnel can quickly access the hyperlinked text which when clicked takes users to the section of the guide they click on as shown in figure 1 below.

Figure 1

1. Protocol Selection	→ Study Start-up Phase
2. Study and Site Feasibility Assessment	
3. Regulatory Submission and Approval	
4. Legal and Financial Review and Approval	
5. Site Activation	
6. Study Execution	→ Active Enrollment Phase
7. Study Closure	→ Close Out Phase

When accessed, the hyperlinks provide personnel with a blanket guide that breaks each listed section into 3 columns titled Activity, Comments, and Resources. Within those sections, users get a brief explanation of prospective instances that crop up in clinical trial management (Activity), comments on how to address those instances (Comments), and finally a hyperlink to access for more information (Resources). While the table and the guide are extremely useful in providing personnel with a blanket overview of what personnel can encounter when in a clinical trial, the guide itself does not provide direct contact information for users within the institution. While the site is password protected on most of the Resource links, if a person new to institution needing direct contact information for their department must navigate the general guide in hopes of finding their direct resource contact. Both guides researched are helpful in respect to the associated institution but lack structure and direct information to assist personnel in accessing useful and applicable resources in managing clinical trials. In researching external institutional guides, a new guide has been established tailored to the Johns Hopkins University Department of Medicine. This thesis acknowledges the short comings within the Johns Hopkins University Department of Medicine. To remedy those shortcomings, a clinical trial management guide for

personnel in DOM departments has been created and provides an easy access breakdown of the structures within the JHU DOM in the clinical trial management world.

Problem Statement

The administrative process for clinical trial management is a complex and varying process for departments even within the same institution. Johns Hopkins University, Department of Medicine, is an example of situations where a number of issues in regards to the procedures surrounding the policies of clinical trial management. In a search of the phrase clinical trial management JHU, one will not be able to find a website link that can guide users through the clinical trial management process. There is no site and policy guide on clinical trial management does not exist. While institutions such as UC Davis Health and the University of Pennsylvania Perelman School of Medicine Office exist and consolidate all aspects of clinical trial management into a one stop guide for their personnel, many research institutions do not provide these necessary road maps. This thesis unlike UC Davis Health and the University of Pennsylvania Perelman School of Medicine Office provides an encompassing guide to provide specific direction and help for anyone within the Johns Hopkins Department of Medicine.

Methodology

This researcher has established a guide in which clinical trial management is done on a small departmental level basis specific to small divisions such as the Division of Allergy and Clinical Immunology which falls under the umbrella of the Johns Hopkins University Department of Medicine. After reviewing models of clinical trial management based on other institutional site guides, personal experience in managing clinical trials, and an extensive survey that illustrates the need for directional information on clinical trial management, this researcher has developed an initial stages clinical trial guide to be used by analysts within the JHU DOM

that are new to managing clinical trials. The early stages of the guide development started with the researcher reflecting on her personal experiences in clinical trial management. Upon reviewing initial stages of a clinical trial, the researcher developed questions for a survey to researchers in the research administration field to identify the issues researchers most commonly come across in managing clinical trials. While the researcher could list the common problems faced when managing a trial, the survey would measure if others faced the same issues. The answers then generated a direction for the guide to take and addresses common issues faced by researchers in the clinical trial management field. In addition to results of the survey, the researcher based several structural elements of the guide on the University of Pennsylvania Perelman School of Medicine OCR Sponsored Study Guide. In incorporating the elemental structure from the Perelman School of Medicine OCR guide, the information throughout the guide is from the researcher's findings on how to manage a clinical trial while following JHU policies and protocols. The researcher leaned on their knowledge of how to find the Johns Hopkins departmental sites, collected the information accessed, and placed the applicable information into the guide. a number of Johns Hopkins department links and In drawing from personal findings, researched guide structures from external institutions, and the answers from the IRB approved research administrator survey developed, to develop the guide as shown in Appendix A.

Project Results

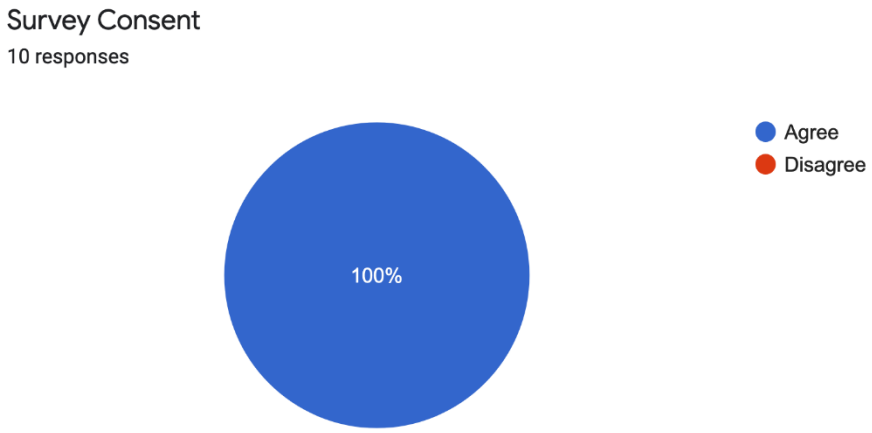
As the surveying of Johns Hopkins personnel is limited and requires extensive IRB review and approval, this researcher crafted a clinical trial management survey specifically recruiting research administrators who are members of the group the National Council of University Research Administration also known as NCURA. The researcher utilized NCURA

message boards to advertise the survey and provided prospective participants with access to the link. The survey was posted on five separate messaging boards on the NCURA website, and was posted twice on the researchers' personal LinkedIn page and was active for more than two months before being closed by the researcher. While the survey was available and accessible, the results only yielded 10 participants. The anticipation from the researcher was that 100 people would take the survey and those answers could either solidify or not the researchers' thoughts. The researcher aimed to collect quantifying data that could address the hypothesis that clinical trial support and management is something missing in large research institutions across the United States. In only receiving a tenth of the expected responses to the survey, the researcher believes that a number of factors contribute to the low result turn out. The stemming factor being the COVID-19 outbreak. The COVID-19 pandemic outbreak initialized a national emergency and a shutdown of the United States in March of 2020 (Schuchat, 2020). The initial shutdown rapidly forced the adjustment of everyday life to incorporate a primarily online based existence for research administrators. All exchanges between researchers and labs were virtualized, and institutions were forced online. Now virtual meetings, emails, and phones calls replaced the everyday in person exchanges adjusting communication flows constantly. While the researcher does not have direct evidence that the pandemic is the sole reason for the low participant participation, it is an easy correlation to make.

The following questions were drafted to assess the clinical trial management deficiencies experienced by research administrators in this field, and confirms the overall hypothesis of this researcher in that the need for a clinical trial management guide is necessary for all research institutions. Comprised of 18 questions, the survey asked qualifying and consenting participants about their involvement with clinical trials within their institution. As this was an anonymous

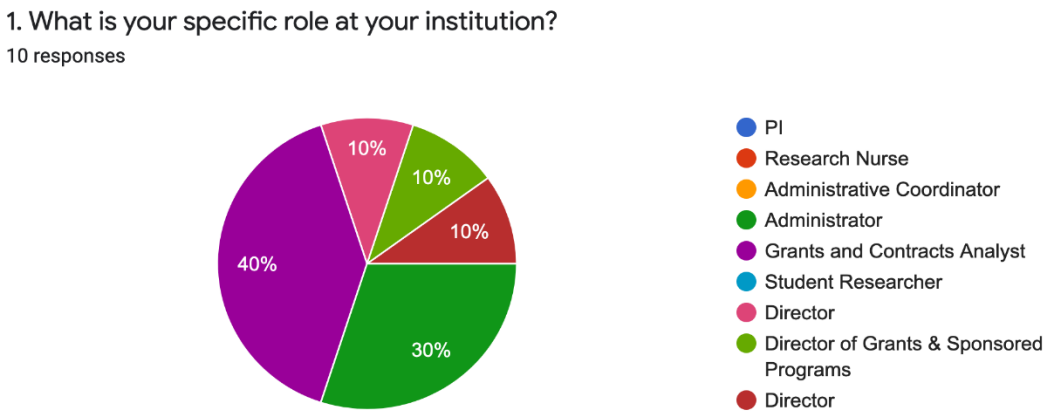
survey, information regarding the respective institutions that the participants work at was not collected to ensure the privacy and anonymity of the participants was maintained. The survey asked participants varying questions regarding their involvement with clinical trials. With NCURA being such a large organization with 7,500 members from over 1,100 colleges, one would assume that the results would vary greatly and in some instances they did (NCURA, 2020). The participant total came to 10 people with varying job titles and experience in the clinical trial management process within their respective institutions. After reading about the purpose of the study, participants were asked to consent to take the survey.

Figure 2



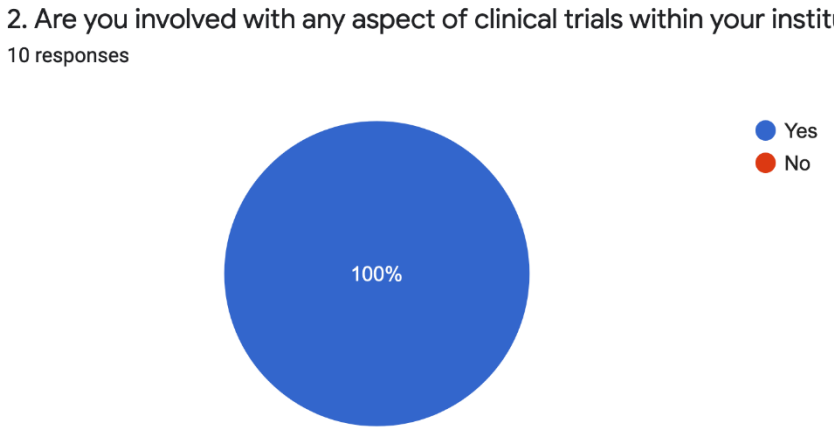
Once consented, participants begin the survey in answering question one which asked what specific role they had within their institution. The job titles of the participants included administrators, research nurses, directors, directors of sponsored projects, and grants and contracts analysts (Best, 2020). This question aimed to highlight the varying roles of personnel involved with clinical trials.

Figure 3



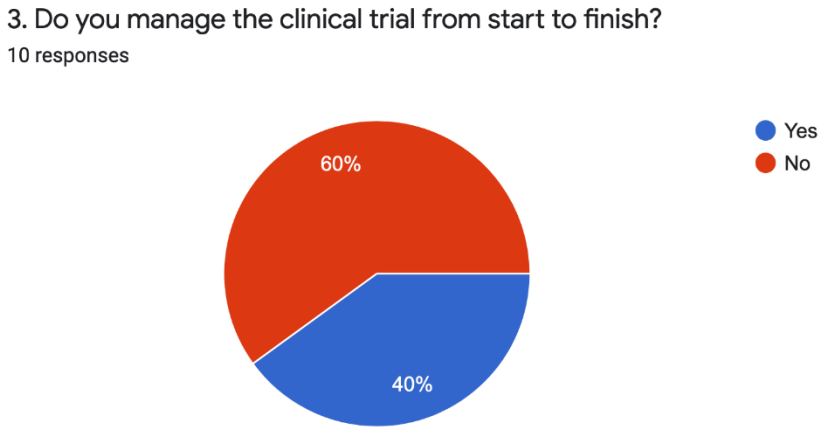
Question 2 then narrowed down the participant pool to whether or not individuals were involved with clinical trials. If they answered no, participants were then not encouraged to continue the survey further.

Figure 4



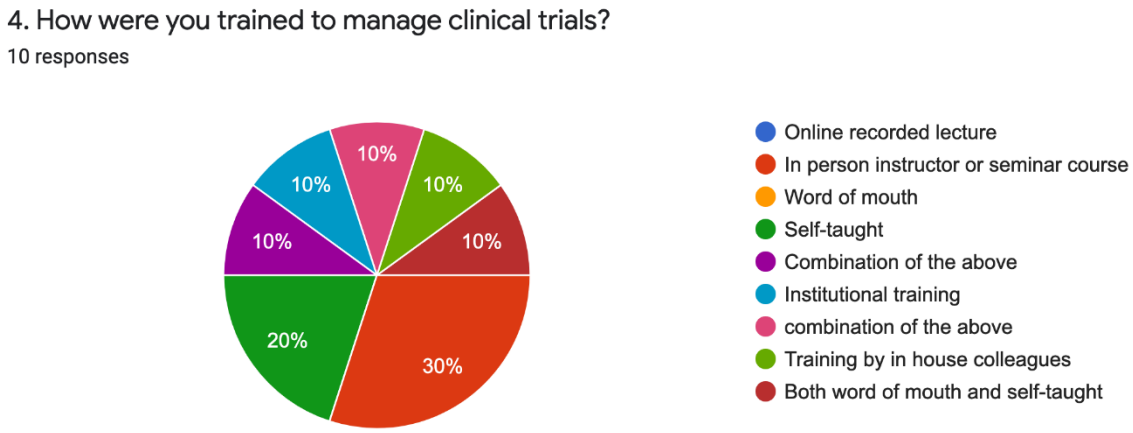
In Question 3, the survey shifted the direction of the questions to analyze how many participants were involved with clinical trials from start to finish. Results yielded at 60% yes and 40% no (Best, 2020).

Figure 5



Questions 4 narrows the survey further down to look at the clinical trial management training received by participants. As the survey results show, the variation in training is apparent. While 50% of participants answered variations of institutional training, training by colleagues, word of mouth, self and being self-taught, 20% of participants answered they taught themselves, and 30% stated in person instruction or seminar courses (Best, 2020).

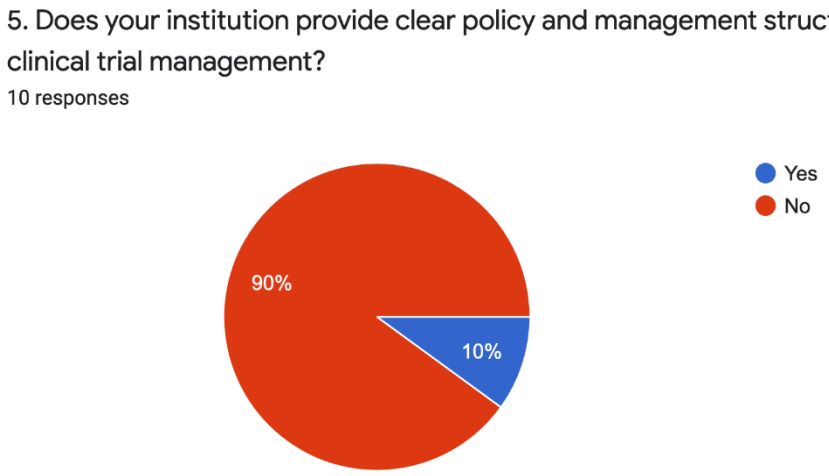
Figure 6



Question 5 of the survey goes on to highlight an interesting deficiency within the research administration field. That while in question 4 personnel did receive some variation of training, in

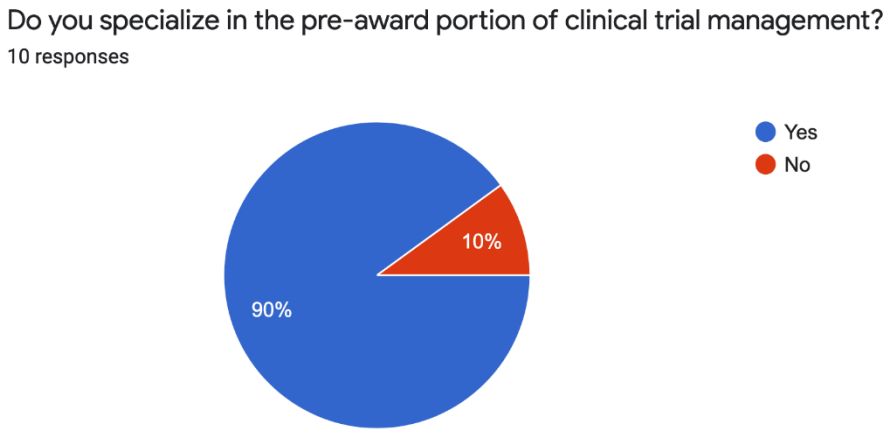
question 5, 90% participants answered that their institutions do not provide personnel with the tools, guides, and clear institutional policy and procedures they need to assist them in managing a clinical trial (Best, 2020).

Figure 7



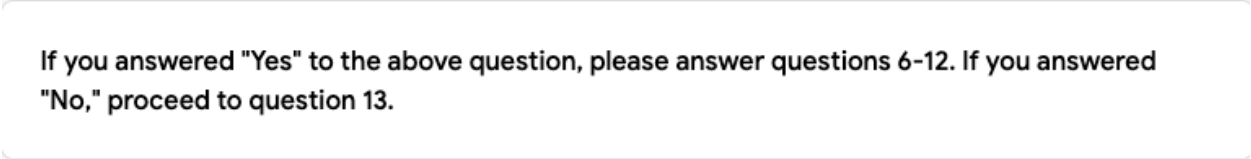
Breaking from the numbered sequence the next question categorized as a Management process Question type asked of participants, asks a pre-award focused section of questions attempting to highlight how involved personnel are in the beginning stages of a clinical trial.

Figure 8



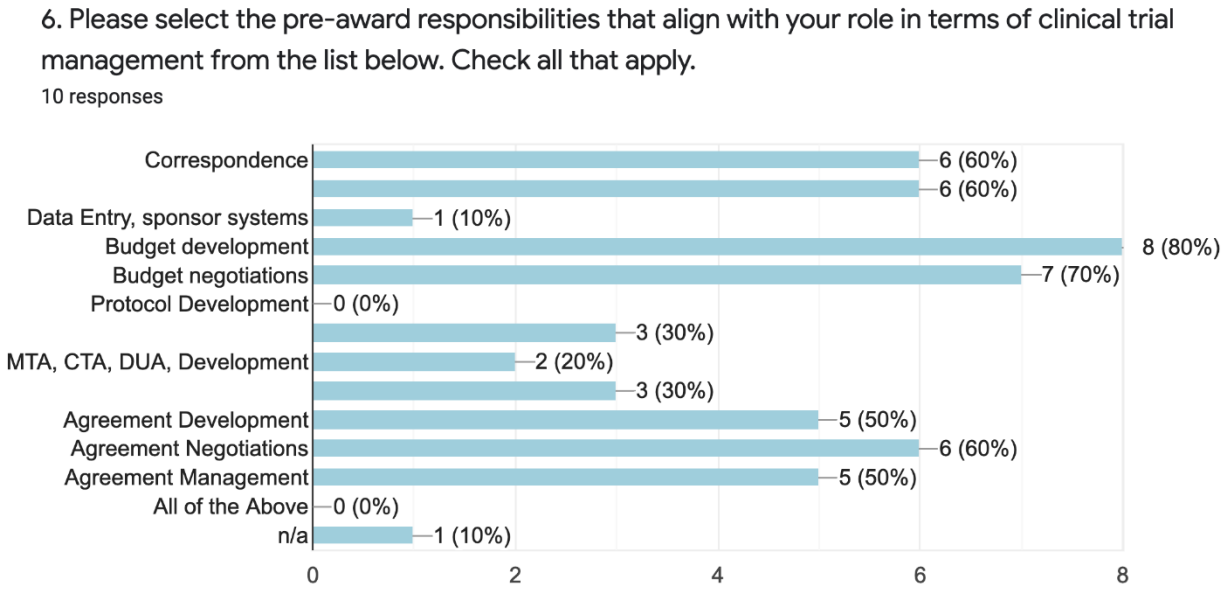
Upon answering the Management process Question, participants were then provided the following prompt:

Figure 9



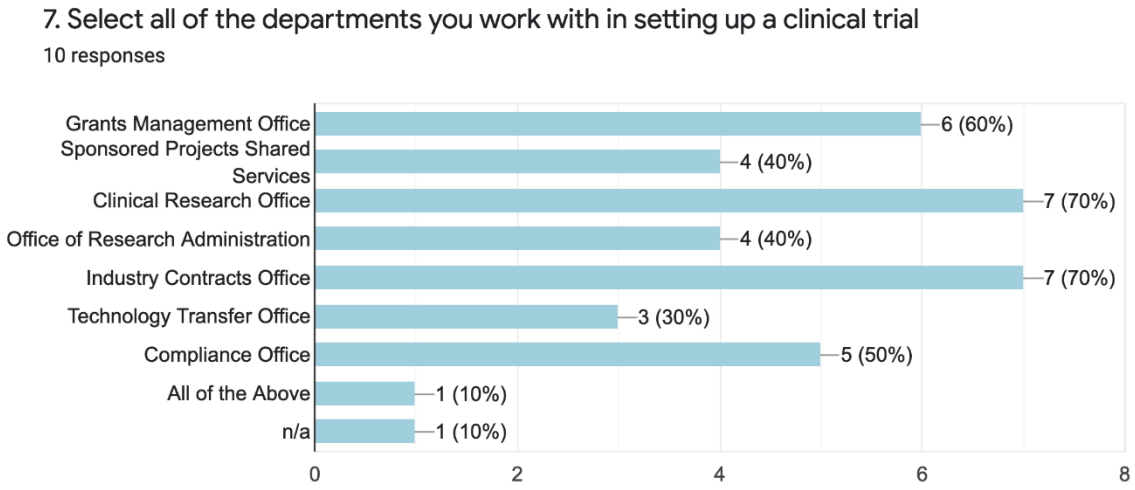
Question 6 then asked participants specifically to answer what areas of pre-award they are responsible for. Of the 10 participants, 60% said they are responsible for correspondence and agreement negotiations, 80% said they're responsible for budget development, 70% budget negotiations, 50% agreement development and agreement management, 30% Protocol Management (Institutional System), MTA, CTA, DUA, Management (Institutional System), 20% MTA, CTA, DUA, Development, and 10% said they were responsible for data entry of sponsored systems (Best, 2020).

Figure 10



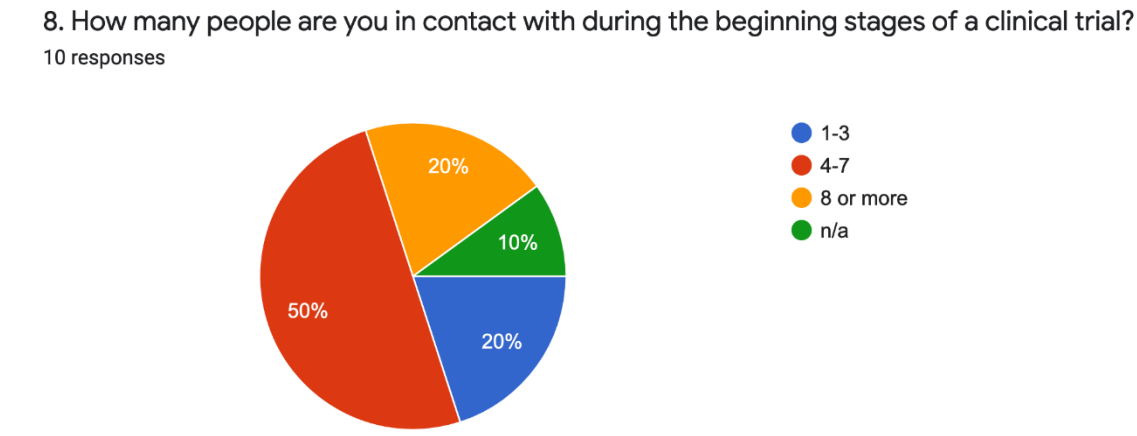
Question 7 then asked participants to answer what departments they work with when setting up a clinical trial. The results, like question 6, yielded 8 participant responses and showed that 70% of participants answered they work with their institutional clinical research office and the industry contracts office, 60% of participants worked with their grants management office, 50% their compliance office, 40% sponsored projects shared services and office of research administration, 30% technology transfer office, and 10% answered they worked with all the above offices (Best, 2020) 1 person was null from this question and answered as such.

Figure 11



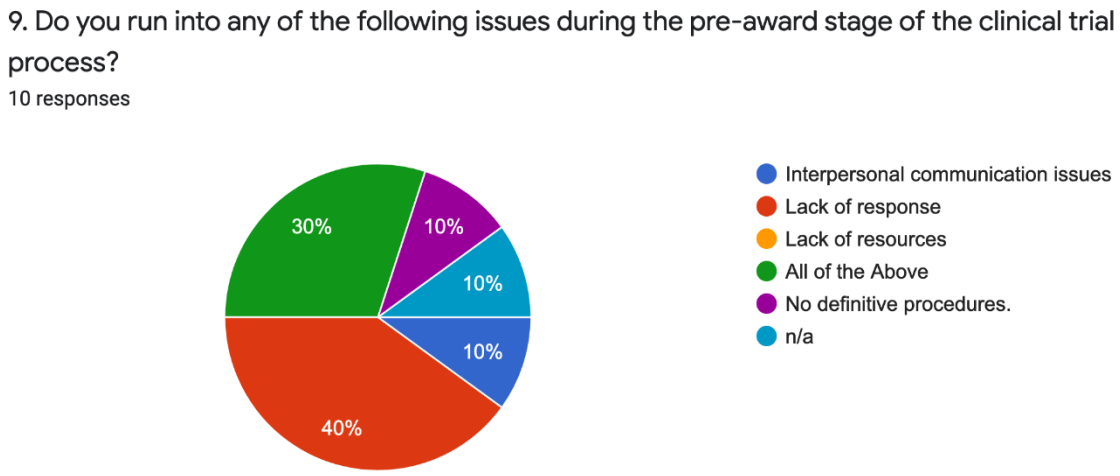
In addition to gauging how many offices participants worked with in the initial stages of a clinical trial, question 8 of the survey aimed to measure the total number of persons participants interact with in the initial clinical trial stages. Question 8 results showed 50% of participants worked with 4-7 people, 10% said 8 or more people, 10% 1-3 people, and one person was listed this question as non-applicable to them (Best, 2020).

Figure 12



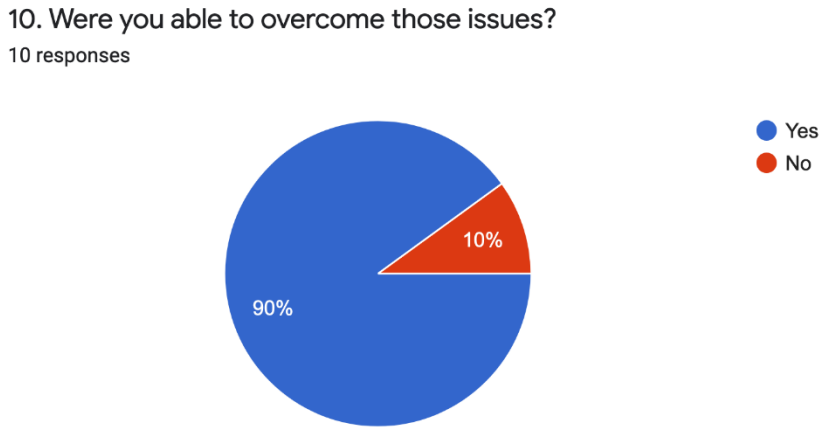
Question 9 of the survey asked participants if they ran into a number of specific issues during the pre-award stages of clinical trials. Of the issues, 40% of participants said they run into lack of response, 30% answered all of the above issues listed including interpersonal communication issues, lack of response, lack of resources, and no definitive procedures, 10% said interpersonal communication issues, 10% no definitive procedures, and 10% said this question was not applicable to them (Best, 2020).

Figure 13



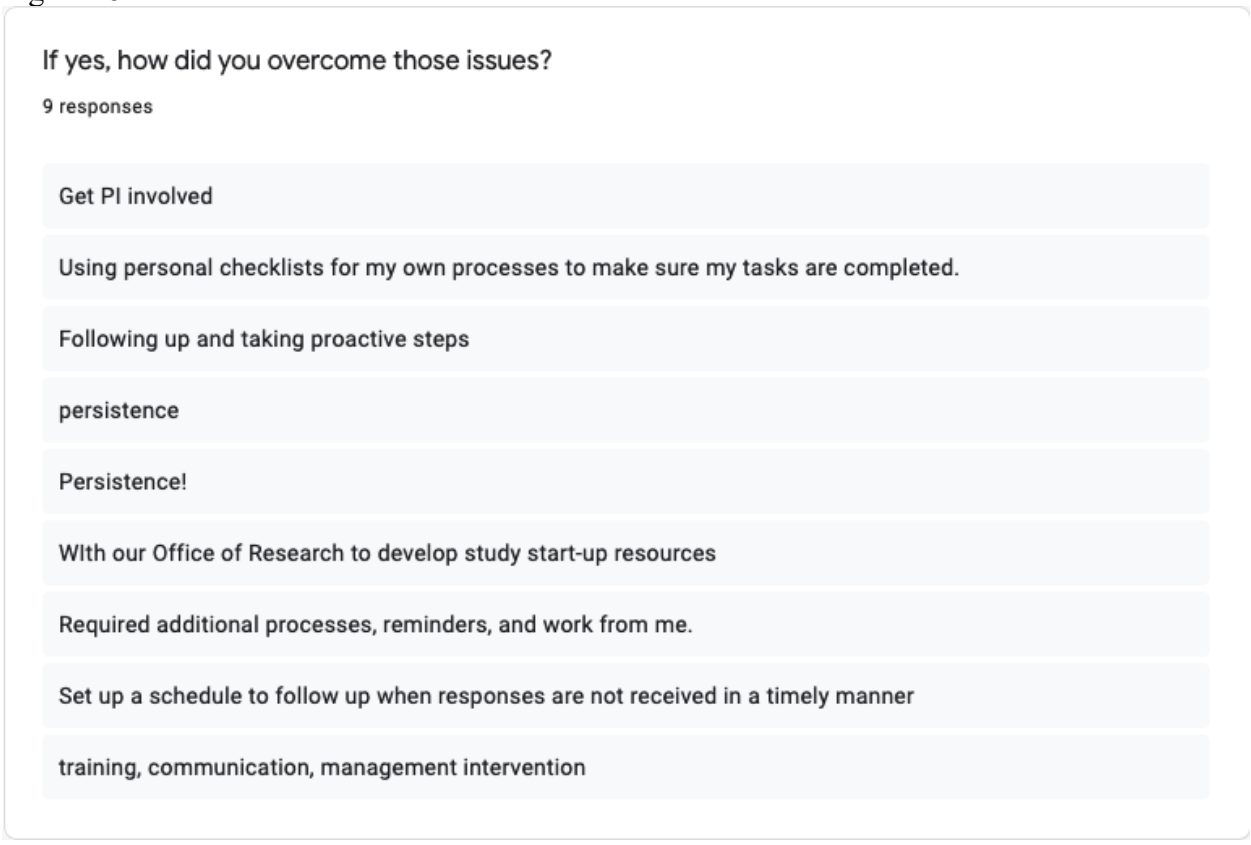
The researcher was then curious to see if those issues were resolved and asked participants in question 10 whether they were able to overcome those issues. Results showed 90% of participants affirmed that they were able to overcome the issues they listed (Best, 2020).

Figure 14



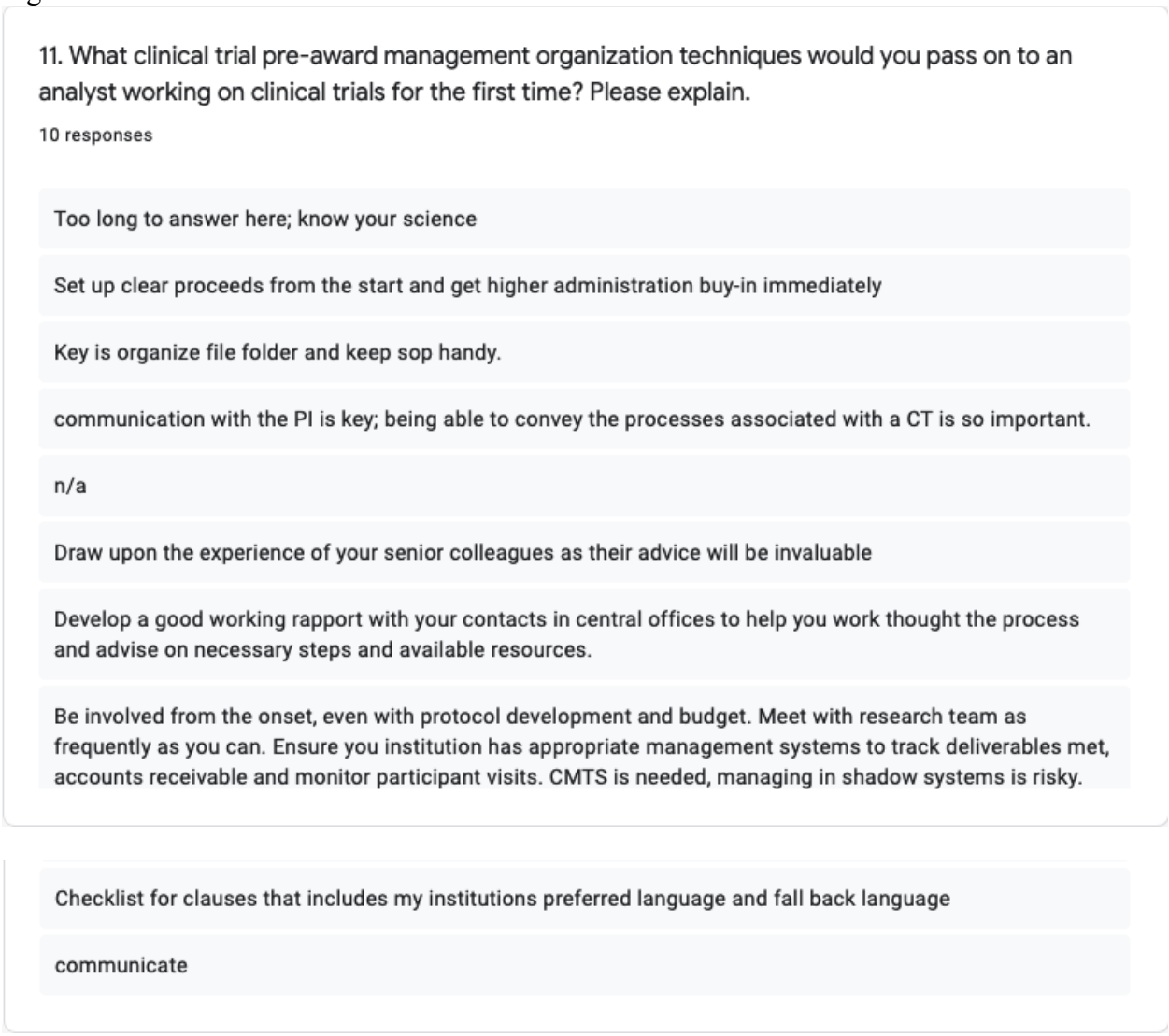
Delving further, the researcher specifically asked a fill in the blank question asking if the participant answered yes to question 10, please provide how they overcame those issues. Of the 10 participants, 9 answered ranging in answers as shown in the screen shot below (Best, 2020).

Figure 15



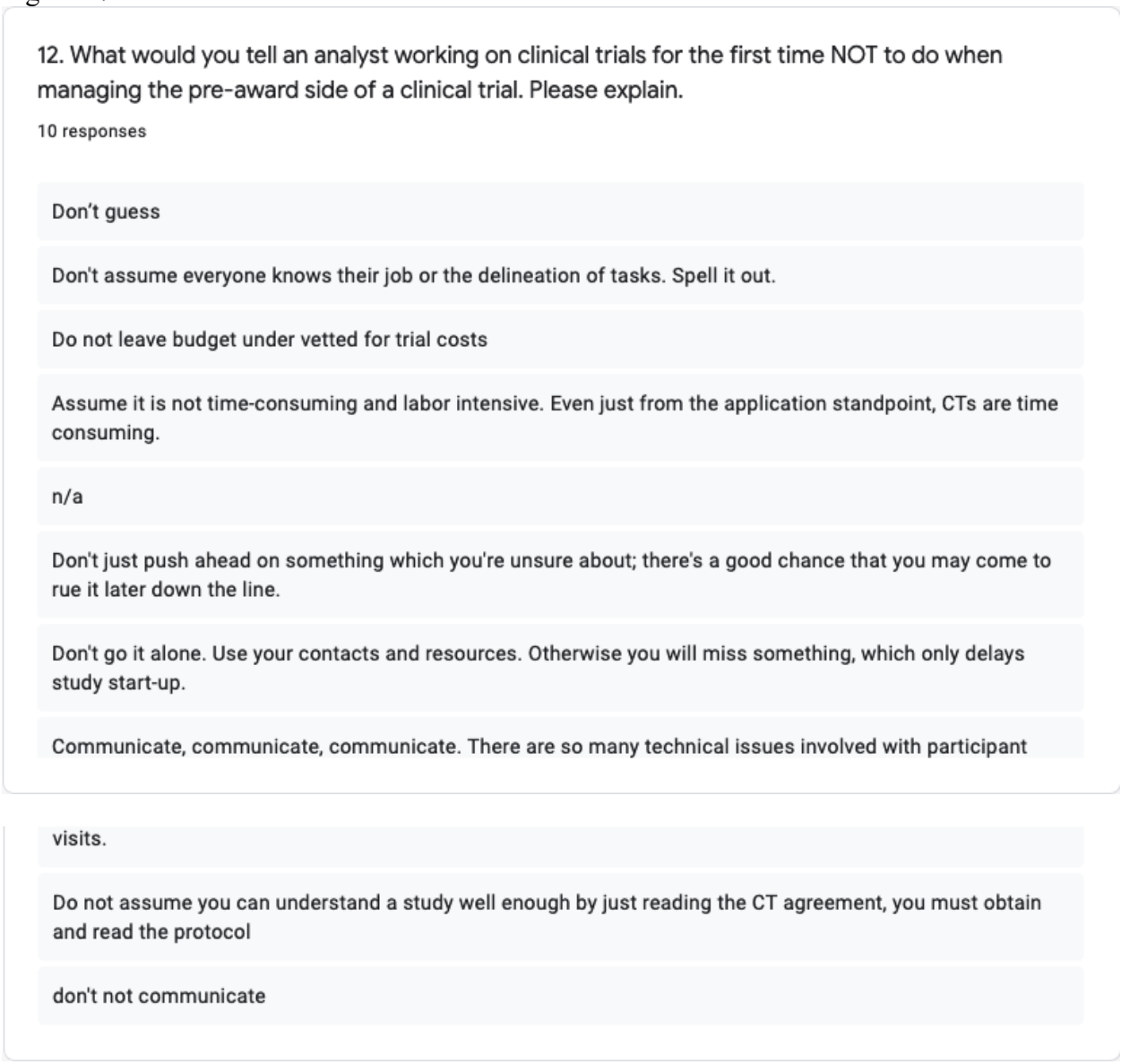
In question 11, the researcher asked participants to provide a short answer as to what organization techniques they would provide for new personnel managing the pre-award side of clinical trials. The short answers ranged in answer as shown in the 2 screen shots below

Figure 16



Question 12 wrapped up the pre-award survey questions and asked participants what they would tell new analysts working in clinical trials for the first time what not to do in terms of pre-award clinical trial management. While the individual answers are provided in the screen shot below, the theme of the answers revolved around the importance of communication.

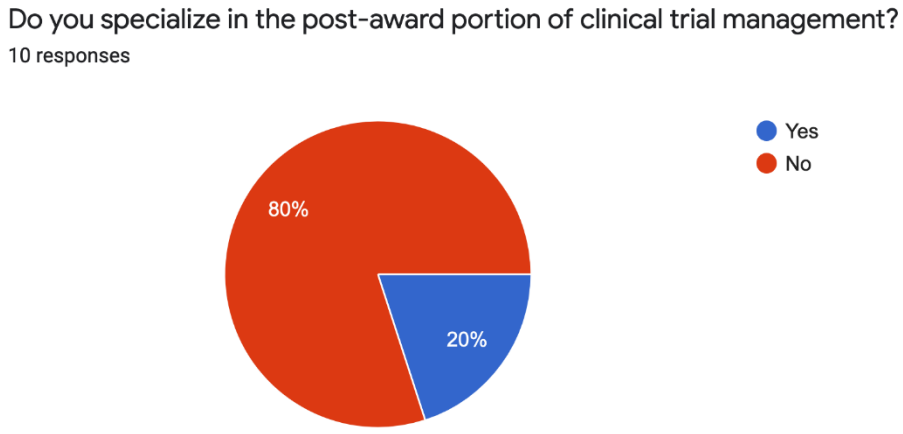
Figure 17



While the first half of the survey primarily focuses on the pre-award side to clinical trial management, most analysts who took the survey also stated that they work clinical trials from start to finish which include the pre to post award cycle of trial management. The post award questions specifically seek out answers to how individuals manage their post award side of clinical trials. Participants were then asked to answer another Management Process Question. Of

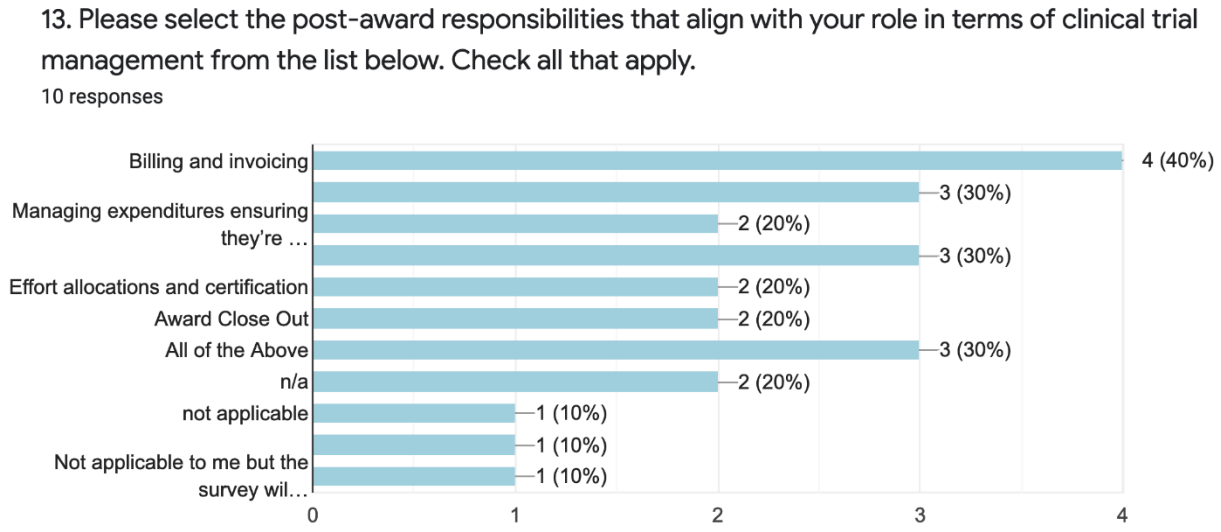
the 10 participants, 80% stated no and 20% stated yes to specializing in post-award management of clinical trials (Best, 2020).

Figure 18



Question 13 asks participants which areas of post award are their responsibility which include duties such as billing and invoicing, tracking patient visits, clinical trial milestones, managing expenditures ensuring they're allowable, allocable, and reasonable, report reconciliations, effort allocations and certification, award close out. While several participants acknowledged the post award side of clinical trial management was non-applicable, a number of participants noted that they were responsible for some or all of the aforementioned duties (Best, 2020). 4 participants said they're responsible for billing and invoicing, 3 said they're responsible for tracking patient visits, clinical trial milestones, report reconciliations, and all of the options listed above, 2 said managing expenditures ensuring they're allowable, allocable, and reasonable, effort allocations and certification, award close out, and 5 people answered this question was not applicable to them.

Figure 19



Where question 13 asks participants what duties they're responsible for, question 14 highlights the frequency analysts must be in contact with PI's regarding clinical trials. While 3 people mentioned the question was not applicable to them, all other participants answered the question differently and answered either weekly, monthly, bi-monthly, or quarterly (Best, 2020).

Figure 20

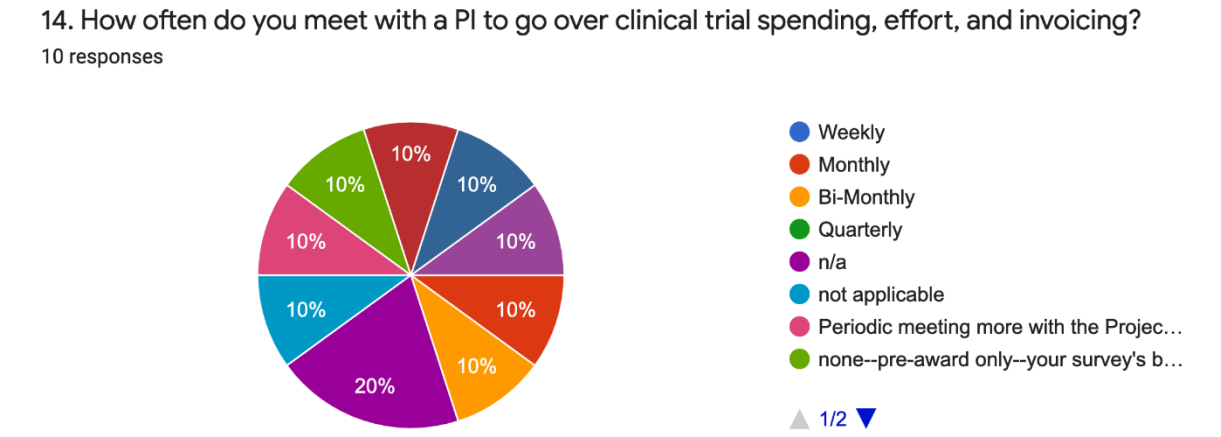
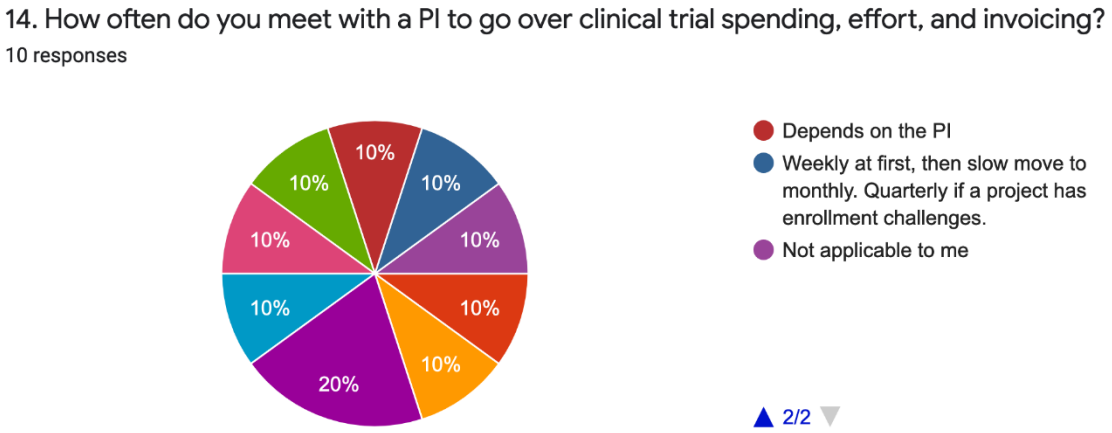
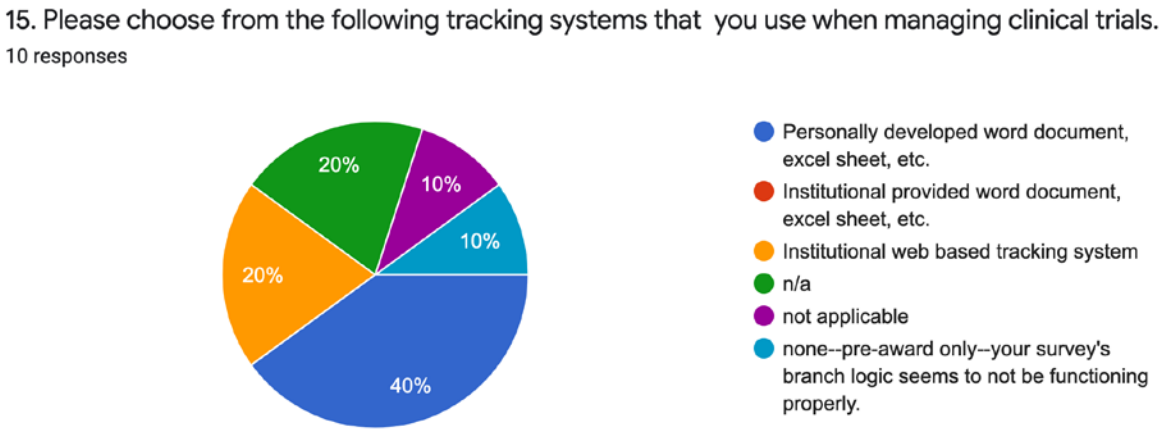


Figure 21



In question 15 the researcher aimed to discover what kind of systems the participants utilized when managing clinical trials. 40% answered personally developed word documents, excel sheets, etc., 20% answered they used institutional web-based tracking systems, and the other 40% answered that this question was not applicable to them (Best, 2020).

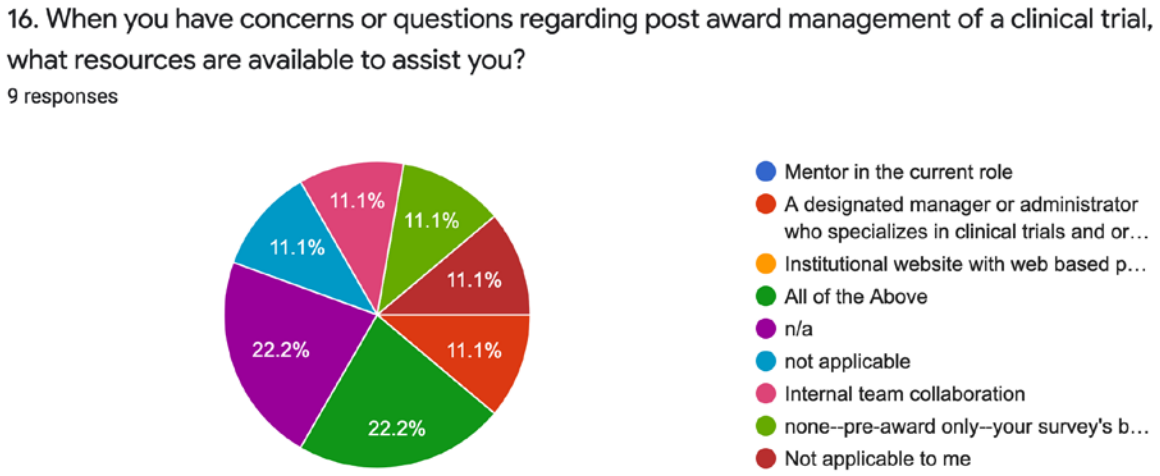
Figure 22



Question 16 asked participants to answer what resources are available to them when they have concerns or questions regarding post award management of clinical trials. Of the 10 participants, only 9 chose to provide an answer. 22.2% answered all of the above from answer selections

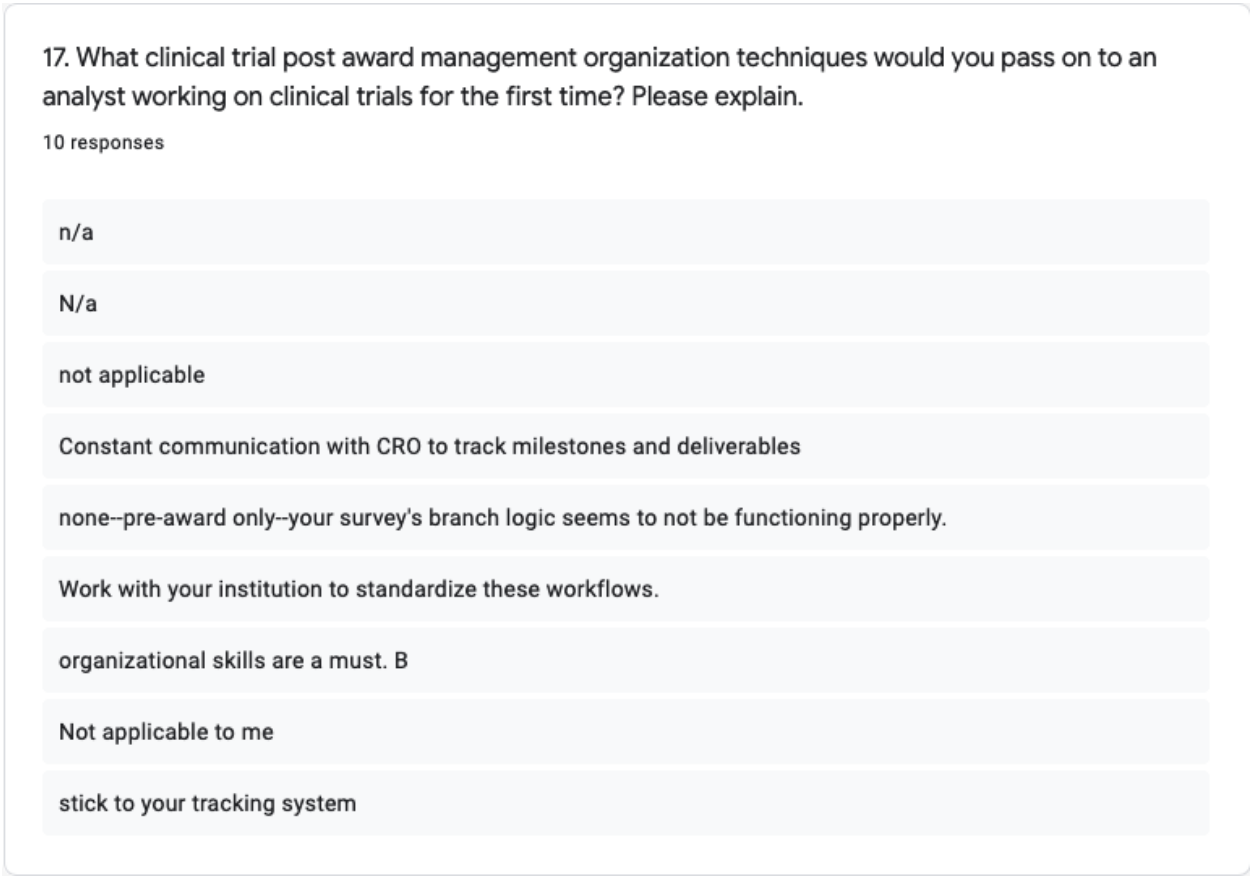
including mentor in current role, a designated manager or administrator who specializes in clinical trials/ sponsored research, and Institutional website with web-based policy guides. 11.1% answered a designated manager or administrator who specializes in clinical trials/ sponsored research, and the remaining participants answered this question was not applicable to them (Best, 2020).

Figure 23



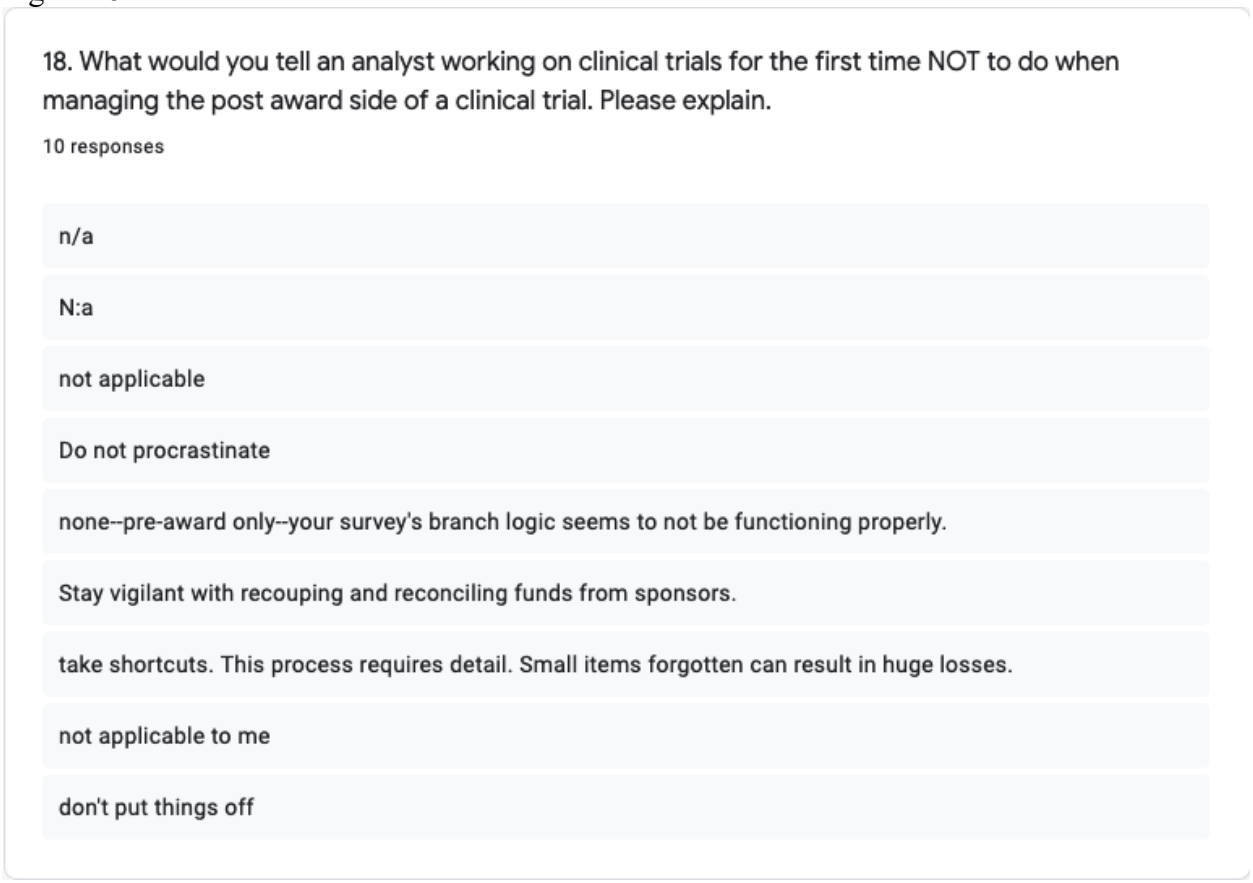
Question 17 then asked participants to provide a short answer to what organizational techniques they would pass along to an analyst working on the post-award side of clinical trial management. 50% of participants provided specific techniques ranging from the importance of communication and organization, while the other 50% answered this question was not applicable to them (Best, 2020).

Figure 24



The final question of the survey question 18, then asked participants what advice they had to give new analysts on what not to do when managing the post-award side of a clinical trial for the first time. 50% answered variations of the importance of time management and organization, and 50% answered the question did not apply to them (Best, 2020).

Figure 25



Conclusion

While the survey results yielded only a small response rate, it is apparent that the clinical trial management deficiencies in the research administration field are wide spread amongst research institutions. To utilize the data and apply it to the initial clinical trial guide in Appendix A, the researcher noticed a few things in the results that lead to the guide development. Upon review of the survey results, the researcher found that the pre-award questions provided more detailed responses from participants. Per the first management process question, 90% of participants answered they specialized in the pre-award stages of clinical trials (Best, 2020). The researcher also noticed that the survey findings had more pre-award data from questions 6 and 13 of the survey. In question 6, 90% of participants answered some variation of the pre-award duties listed (Best, 2020). When compared to the same question asked regarding post-award duties in

question 13, only 50% of participants answered the duties were relevant to them (Best, 2020). With the vast majority of participants saying they specialized in pre-award, the researcher decided to focus on creating a pre-award initial clinical trial guide. Due to the pre-award responses, and from question 5 showing that 90% of participants said they had no clear clinical trial management structure, the researcher decided to tailor their guide to breakdown the JHU DOM pre-award clinical trial process in the form of the Appendix A guide (Best, 2020).

The lack of managerial support, total self-guidance and reliance, and minimal access to training or institutional support guides are a few of the pressing and detrimental issues that analysts are facing in regards to clinical trial management. The research collected, and the literature reviewed, demonstrates the ever-present need for institutional support and training, as well as institutional based guides to assist all analysts working in the clinical trial management field. The researcher's guide in Appendix A is a positive step forward in providing initial support for analysts managing clinical trials in the JHU DOM.

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Figure 26

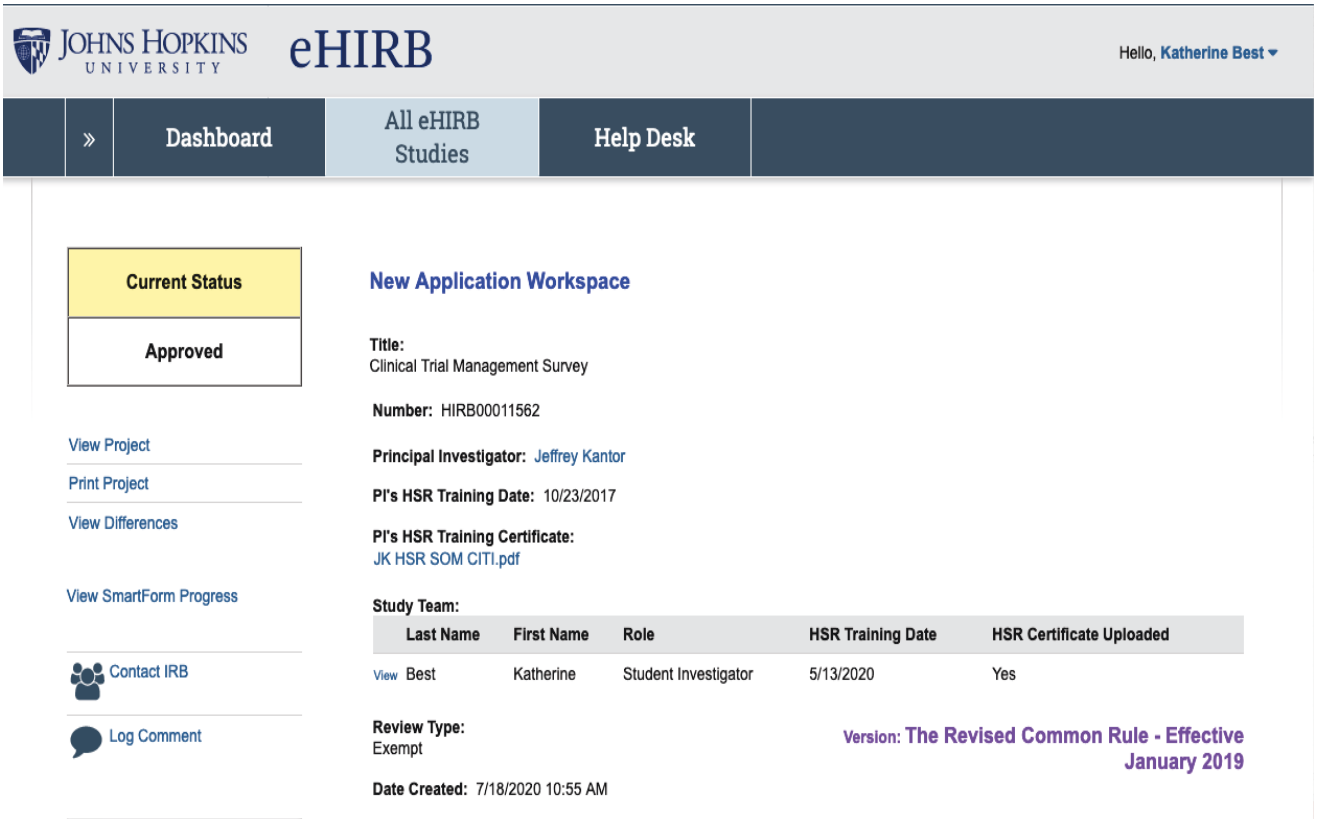

JOHNS HOPKINS UNIVERSITY
eHIRB
Hello, Katherine Best
»
Dashboard
All eHIRB Studies
Help Desk
Current Status
Approved
View Project
Print Project
View Differences
View SmartForm Progress
Contact IRB
Log Comment
New Application Workspace
Title:
Clinical Trial Management Survey
Number: HIRB00011562
Principal Investigator: Jeffrey Kantor
PI's HSR Training Date: 10/23/2017
PI's HSR Training Certificate:
JK HSR SOM CITI.pdf
Study Team:
Last Name
First Name
Role
HSR Training Date
HSR Certificate Uploaded
View Best
Katherine
Student Investigator
5/13/2020
Yes
Review Type:
Exempt
Version: The Revised Common Rule - Effective January 2019
Date Created: 7/18/2020 10:55 AM

Figure 27

Clinical Trial Management Deficiencies

Clinical trial research is performed across the world and is an important cornerstone within the field of research administration.
The management work done by research administrators is crucial to the successes of clinical trials, because that work often determines whether funding is obtained, lost, or kept based on how the trial is managed within a given institution.
Your input is needed to:

- Assess the varying clinical trial management structures within research institutions
- Highlight the common and current clinical trial management deficiencies in the field
- Provide a path to prospective solutions of common clinical trial issues

Are you eligible?

- 18 Years or older
- are a professional in the research administration field
- agree to voluntarily participate in this study

If you fit the eligible criteria listed above, please click here to take survey

Clinical Trial Management Survey
Thesis Survey Questionnaire
Introduction

Clinical trial research is performed across the world and is an important cornerstone within the field of research administration. The management work done by research administrators is crucial to the successes of clinical trials, because that work often determines whether funding is obtained, lost, or kept, based on how the trial is managed within a given institution. Nevertheless, the protocols for how clinical trial management is done varies greatly from one research institution to the next, which can hamper the effectiveness of the work we do.

In an attempt to remedy these issues, Katherine Best, a graduate student in the Research Administration program at Johns Hopkins University, is researching these variations to clinical trial management styles at research institutions across the United States. She hopes to isolate common clinical trial management issues and use those findings to develop a universal clinical trial management guide that will help to streamline administration processes, thereby increasing departments' efficiency and making the complexities of this work easier to understand for newcomers to the field.

You have been selected to take part in this survey because of your role in the research administration field. Your responses are important to the success of this research project even if you do not typically work on clinical trials.

In completing this survey, you are consenting to be in this research study. Your participation is voluntary, and you can drop out at any time. All information will be stored in a password-protected format. To protect your confidentiality, the survey does not contain information that will personally identify you. The results of this study will be used for scholarly purposes only and may be shared with Johns Hopkins University personnel.

Thank you for participating!

By selecting the agree button, you are confirming that you:

1. are 18 years or older
2. are a professional in the research administration field
3. have read the information above
4. agree to voluntarily participate in this study

    a. Agree
    b. Disagree

General Questions

1. What is your specific role at your institution?
    a. PI
    b. Research Nurse
    c. Administrative Coordinator
    d. Administrator
    e. Grants and Contracts Analyst
    f. Other___
2. Are you involved with any aspect of clinical trials within your institution?
    a. Yes
    b. No
3. Do you manage the clinical trial from start to finish?
    a. Yes
    b. No
4. How were you trained to manage clinical trials?
    a. Online recorded lecture
    b. In person instructor or seminar course
    c. Word of mouth
    d. Self-taught
    e. Other___
5. Does your institution provide clear policy and management structure guidelines regarding clinical trial management?
    a. Yes
    b. No

Management Process Questions

Do you specialize in the Pre-Award portion of clinical trial management?

a. Yes
b. No

If you answered "Yes" to the above question, please answer questions 7-13. If you answered "No," proceed to question 14.

6. Please select the pre-award responsibilities that align with your role in terms of clinical trial management from the list below. Check all that apply.

a. Correspondence

b. Data Entry, institutional systems
c. Data Entry, sponsor systems
d. Budget development
e. Budget negotiations
f. Protocol Development
g. Protocol Management (Institutional System)
h. MTA, CTA, DUA, Development
i. MTA, CTA, DUA, Management (Institutional System)
j. Agreement Development
k. Agreement Negotiations
l. Agreement Management
m. All of the above
n. Other_____

7 Select all of the departments you work with in setting up a clinical trial
a. Grants Management Office
b. Sponsored Projects Shared Services
c. Clinical Research Office
d. Office of Research Administration
e. Industry Contracts Office
f. Technology Transfer Office
g. Compliance Office
h. All of the above
i. Other____

8 How many people are you in contact with during the beginning stages of a clinical trial?
a. 1-3
b. 4-7
c. 8 or more
d. Other___

9 Do you run into any of the following issues during the pre-award stage of the clinical trial process?
a. Interpersonal communication issues
b. Lack of response
c. Lack of resources
d. All of the above
e. Other_____

10 Were you able to overcome those issues?
a. Yes
b. No
c. If yes, how did you overcome those issues?

11 What clinical trial pre award management organization techniques would you pass on to an analyst working on clinical trials for the first time? Please explain.

12 What would you tell an analyst working on clinical trials for the first time NOT to do when managing the pre award side of a clinical trial. Please explain.

Do you specialize in the Post-Award portion of clinical trial management?
a. Yes

b. No

If you answered "Yes" to the above question, please answer questions 14-19. If you answered "No," then proceed to the end of the survey.

13 Please select the post-award responsibilities that align with your role in terms of clinical trial management from the list below. Check all that apply.
   a. Billing and invoicing
   b. Tracking patient visits, clinical trial milestones
   c. Managing expenditures ensuring they're allowable, allocable, and reasonable
   d. Report reconciliations
   e. Effort allocations and certification
   f. Award Close Out
   g. All of the above
   h. Other___
14 How often do you meet with a PI to go over clinical trial spending, effort, and invoicing?
   a. Weekly
   b. Monthly
   c. Bi-Monthly
   d. Quarterly
   e. Other____
15 Please choose from the following tracking systems that you use when managing clinical trials.
   a. Personally developed word document, excel sheet, etc.
   b. Institutional provided word document, excel sheet, etc.
   c. Institutional web based tracking system
   d. Other___
16 When you have concerns or questions regarding post award management of a clinical trial, what resources are available to assist you?
   a. Mentor in the current role
   b. A designated manager or administrator who specializes in clinical trials and or sponsored research?
   c. Institutional website with web based policy guides?
   d. All of the above
   e. Other___
17 What clinical trial post award management organization techniques would you pass on to an analyst working on clinical trials for the first time? Please explain.
18 What would you tell an analyst working on clinical trials for the first time NOT to do when managing the post award side of a clinical trial. Please explain.

Thank you for your participation! Your responses will help Katherine's research to improving the field of research administration.

Appendix A: Department of Medicine Initial Clinical Trial Management Guide

Created By: Katherine Best
Grants and Contracts Analyst Allergy and Clinical Immunology Division
Department of Medicine School of Medicine Johns Hopkins University

December, 2020

Table of Contents

Introduction

This guide is intended to be used as a resource in the initial stages of clinical trials. Johns Hopkins University analysts new to managing clinical trials currently do not have access to a clinical trial guide assisting them in the initial stages of managing clinical trials. While there is information available, there is currently no guide that pieces together the initial steps and stages of what departments are involved in clinical trials, the forms required by those departments, and the submission requirements by the university. This guide closes that structural gap and provides researchers, analysts, and any personnel working on clinical trials with access to clinical trial support in the shape of the guide produced below.

Relevant Definitions

Clinical Trial

- The World Health Organization (WHO) defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."
- The U.S. National Institutes of Health (NIH) defines a clinical trial as: " A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

Clinical Trial Agreement

- A Clinical Trial Agreement (CTA) is a legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.
  https://ccts.osu.edu/content/clinical-trial-agreement
  https://research.jhu.edu/jhura/training-and-resources/glossary-of-terms-and-acronyms/#C

COEUS,

- JHU's sponsored projects proposal submission software.
  https://research.jhu.edu/oris/wp-content/uploads/sites/3/2016/04/oris-tip-sheets-new-users.pdf

Consent Form

- A document with important information about a medical procedure or treatment, a clinical trial, or genetic testing. It also includes information on possible risks and benefits. If a person chooses to take part in the treatment, procedure, trial, or testing, he or she signs the form to give official consent.
  https://www.cancer.gov/publications/dictionaries/cancer-terms/def/consent-form

Data Use Agreements (DUA)

- Where faculty are receiving or sharing human subject data as part of a research collaboration, they will need to ensure that an appropriate Data Use Agreement or other form of research collaboration or confidentiality agreement is in place.
  https://homewoodirb.jhu.edu/documents/data-use-agreements-dua/

Institutional Review Board (IRB)

- An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
  https://grants.nih.gov/grants/glossary.htm#P

Investigator's Brochure (IB)

- The Investigator's Brochure (IB) is a comprehensive compilation of clinical and nonclinical data on the investigational product (drug, supplement, device or other product) maintained by a drug developer or investigator that contains the body of

information about the investigational product obtained before and during a drug trial. The IB is a document of critical importance throughout the drug development process and is updated with new information as it becomes available.
https://www.research.colostate.edu/ricro/qa/investigators-brochure/

Material Transfer Agreement (MTA)

- A legal document defining the conditions under which research or other materials can be transferred and used among research laboratories.
https://grants.nih.gov/grants/glossary.htm#P

My Research and Agreement/Application Place (MyRAP)

- MyRAP is a new Johns Hopkins University-wide online system developed to provide PIs and their administrative Partners real-time access to the status of their research agreements and contracts as they are being reviewed, negotiated and processed by the Offices of Research Administration (ORA).
https://res.jhu.edu/system_myrap.html

A non-disclosure agreement (NDA), also known as a confidential disclosure agreement (CDA) or secrecy agreement

- Provides parameters and protections to the parties exchanging confidential or proprietary (non-public) information. Any Johns Hopkins University faculty, student, or employee intending to disclose such information to a third party should execute a NDA before doing so.
https://ventures.jhu.edu/technology-transfer/non-disclosure-agreements/

Pre-Award Phase

- The pre-award phase represents the beginning of the grant lifecycle, which includes announcing opportunities, submitting applications, and reviewing applications.
https://www.grants.gov/learn-grants/grants-101/pre-award-phase.html

Principal Investigator

- The person(s) in charge of a clinical trial or a scientific research grant. The principal investigator prepares and carries out the clinical trial protocol (plan for the study) or research paid for by the grant. The principal investigator also analyzes the data and reports the results of the trial or grant research. Also called PI.
https://www.cancer.gov/publications/dictionaries/cancer-terms/def/principal-investigator

Prospective Reimbursement Analysis (PRA)

- Is a systematic review of a clinical research study protocol, draft contract and sponsor budget, proposed Informed Consent Form (ICF) cost language and other documents, when applicable, including the Notice of Grant Award (NOGA), Investigator's Brochure (IB) and information regarding the FDA status of the investigational item(s). PRAs are necessary for all research studies that have the potential to generate a hospital facility charge and/or professional charge.
https://ictr.johnshopkins.edu/wp-content/uploads/2019-CRSS-Final.pdf

Protocol

- Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.
https://grants.nih.gov/grants/glossary.htm#P

Scope of Work

- The aims, objectives, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant's objectives. This includes the research or training plan included with the original grant application, along with any approved modifications. https://grants.nih.gov/grants/glossary.htm#S

Sponsor

- One or more designated individual(s) responsible for providing the fellow with research training and career guidance throughout the grant award period. https://grants.nih.gov/grants/glossary.htm#S

Table 1

Offices to Know

Office	Description	Contact Information
Clinical Research Support Services (CRSS)	Is an office created to provide centralized support and ongoing instruction to clinical research teams regarding Prospective Reimbursement Analysis (PRA), budget development, budget negotiation with commercial sponsors.	Clinical Research Support Services (CRSS) 750 E Pratt St 14th fl Phone 410-361-8362 Fax number: 410-361-8363 Email: CRSS@jhmi.edu Website: hopkinsmedicine.org Budget Contact: Lisa Wallace Associate Director ORASOM Admin Res Clinical Research Contract Phone: 410-361-8359 Email: lwalla10@jhmi.edu PRA Development Contact: Cindy Elliott Clinical Research Support Services Manager Phone: 410-361-8360 Email: cellio14@jhmi.edu Clinical Trial Status Contact: Jared Nipper Sponsored Projects Associate Office of Research Administration Phone: 410-361-8365 Email: jnipper@jhmi.edu

Department of Medicine (DOM) Research Administration & Support Team (RAST)	The Department of Medicine Research Administration & Support Team (RAST) is a resource for sponsored research that maintains compliance and integrity in award management, ensures excellent customer service and provides sponsored research training.	Department of Medicine (DOM) Research Administration & Support Team (RAST) 1830 E Monument St Ste 9043 Contact: Elaine Thomas Grants & Contracts Manager JHU School of Medicine Department of Medicine Research Administration Services Phone: 410-614-6620 Email: ethomasa@jhmi.edu
Office of Research Administration (ORA)	The Office of Research Administration (ORA) reviews and negotiates all grant and contract proposals and awards for the School of Medicine, including commercially-sponsored clinical research agreements. This includes all federal contracts, foundation awards, all grant awards, all contracts for clinical, pre-clinical and non-clinical research, consulting agreements, unfunded collaboration agreements, data use agreements, materials transfer agreements, confidentiality/nondisclosure agreements, and all outgoing subawards/subcontracts.	SOM Office of Research Administration Edward D. Miller Research Building, Suite 117 733 N. Broadway, Baltimore, MD 21205 Phone: 410-955-3061 Fax: 410-502-7832 Website: hopkinsmedicine.org/research Signing Official /Reviewer Contact: Sharel Brown Associate Director, Grants / Authorized Official Office of Research Administration Phone: 443-287-9326 Email: sbrown80@jhmi.edu
Office of Research Administration (ORA) Clinical Research Contracting (CRC)	The Clinical Research Contracting group reviews and negotiates all commercial Clinical Research agreements.	SOM Office of Research Administration Edward D. Miller Research Building, Suite 117 733 N. Broadway, Baltimore, MD 21205 Phone: 410-955-3061 Fax: 410-502-7832 Website: hopkinsmedicine.org/research

		Johns Hopkins Medicine Clinical Research Administration 750 E. Pratt Street 14th Floor Baltimore, MD 21202 Phone 410-361-8362 Fax number: 410-361-8363 Website: hopkinsmedicine.org/research Initial Contact: Patricia Previll Sponsored Projects Specialist Office of Research Administration Phone: 410-614-3636 Email: paprevill@jhmi.edu Signing Official Contact: Carlos Braxton Associate Director ORA SOM Admin Res General Administration Phone: 410-955-8937 Email: cbraxto1@jh.edu Contract Reviewer Contact: Jennifer M. Williams, M.S., J.D. Contract Associate Office of Research Administration Phone: 410-361-8369 Email: jmwilliams1@jhmi.edu
JHTV Johns Hopkins University Tech Ventures	JHTV aims to maximize the impact of Johns Hopkins University's research excellence by facilitating the translation and commercialization of discoveries into accessible **technologies**, products and services that benefit society. Find Funding. Explore Companies.	Johns Hopkins Technology Ventures 1812 Ashland Avenue, Suite 110 Baltimore, MD 21205 Contact: Jackie N. Anderson Technology Transfer Specialist Phone: 410-502-6146 Email: jander77@jhu.edu
Pharmacy and Investigational	Clinical research within The Johns Hopkins Health-System is supported	The Johns Hopkins Hospital – Osler Investigational Drug Service

Drug Service (IDS) at The Johns Hopkins Hospital	by Investigational Drug Service (IDS) staff at The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Sibley Memorial Hospital, Suburban Hospital, All Children's Hospital, and at Howard County General Hospital (HCGH). These locations all provide comprehensive pharmacy services to support clinical trials, such as:
	
	• Pharmacist review of all medication orders and monitoring parameters, if applicable
	• Drug preparation and dispensing
	• Drug information to patients and healthcare team
	• Drug management, accountability and regulatory support for clinical trials (Note: Suburban and HCGH do not use electronic inventory management at this time)
	• Support development of clinical trials, including:
	  ○ Protocol Review
	  ○ Development of pharmacy budget and invoice for services
	  ○ Review of Investigational Drug Data Sheet (IDDS)
	  ○ Review of order sets
	  ○ Participate in quality assurance activities for clinical protocols
	  ○ Staff education
		Location: Osler 100
		Hours: Monday through Friday, 7:30 AM to 5:30 PM
		Phone: 410-955-6337 or 410-955-4505
		Fax: 410-614-8074
		Pager: 410-283-2936
		Website: hopkinsmedicine.org/pharmacy
		
		Contact: Jim Monolakis, PharmD, Investigational Drug Service Manager
		Phone: 410-550-2747
		Email: bayviewIDS@jhmi.edu

Sponsored Projects Shared Services (SPSS)	Sponsored Projects will set up and maintain each award's master data elements and monitor awards for compliance with applicable regulations and institutional	Johns Hopkins at Keswick 3910 Keswick Road, 5th Floor Baltimore, MD 21211 Phone: 443-997-8151 Fax: 443 -997-8419

	policies. It will complete financial reporting to external sponsors and close out awards within the SAP system according to sponsor requirements. It will serve as a resource to departmental administrators and researchers in all aspects of post-award financial administration.	School of Medicine and JHHS Email: SponsoredProjectsJHM@jhu.edu Contact: Erika Tringali Sponsored Projects Accountant Supervisor Department of Medicine Johns Hopkins University Phone: 443-997-8967 Email: Erika.Tringali@jhu.edu

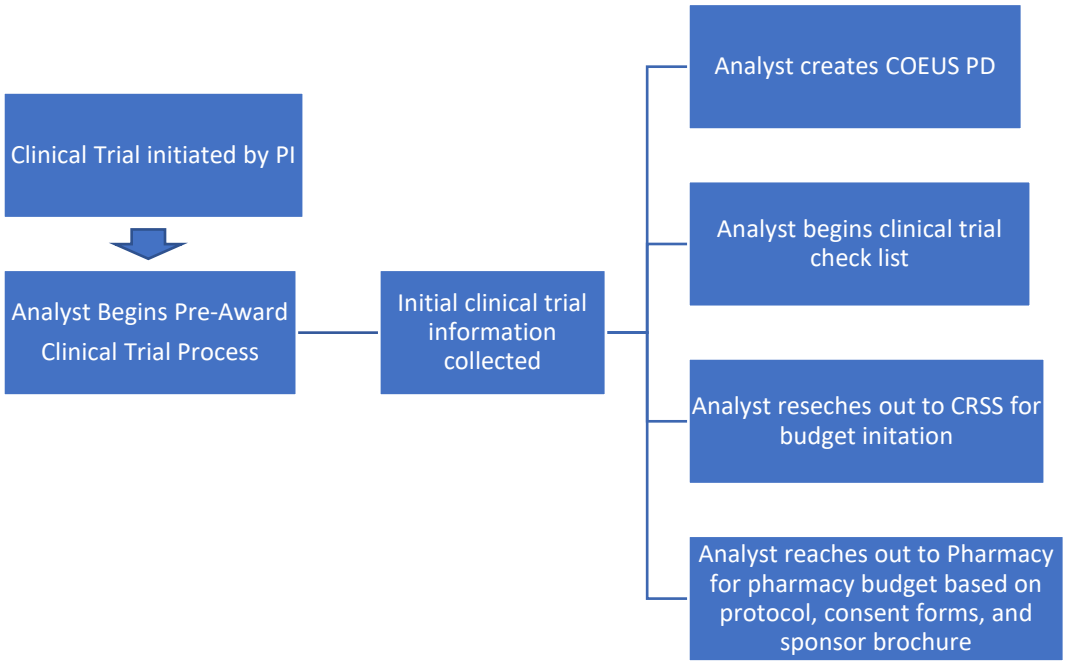
Initial Stages of Clinical Trial Flow Chart

Organization of clinical trials is essential in the early stages of a prospective project. In the flow chart found below, the beginning of a clinical trial starts with PI approaching their personnel with the information that a prospective clinical trial is in the works. From there, the analyst then begins the pre-award clinical trial process, and starts by collecting the necessary information needed from the PI and their study team. The information needed includes, but is not limited to;

1. Project title
2. Protocol IRB Number
3. Scope of work
4. Consent Form
5. Investigator's Brochure (IB)
6. Agreement in word format
7. Sponsor contact for contract information
8. Email from the sponsor stating they will support this project
9. Email including all documents sent over by the sponsor for review and negotiation (inclusive of MTA, DUA, CDA, DUA, etc., and other contractual documents to be reviewed and negotiated documents)
10. CRSS budget checklist completed
11. CRSS supplemental information sheet completed
12. COEUS questionnaires/PI Certification completed

The analyst must then simultaneously start the COEUS PD, clinical trial checklist, reach out to CRSS to initiate the PRA, and reach out to pharmacy to begin the pharmacy budget.

Figure 28



Email Examples to PI, CRSS, Pharmacy

Analysts reaching out to their PI's should ensure their email includes all of the required documents required by the DOM ORA approvers who review the submitted COEUS PD, CRSS, and the pharmacy. All documents should then be loaded into the COEUS PD system, and emailed to the appropriate contact information. Training and the COEUS PD instructions can be found via the links below.

- COEUS Training: https://research.jhu.edu/oris/first-steps/
- COEUS Guide: https://research.jhu.edu/oris/wp-content/uploads/sites/3/2016/04/oris-user-guides-roles.pdf

Figure 29

Dear Dr.____, and research study team,

To initiate this clinical trial within the Johns Hopkins University system, I will need the following information at your earliest convenience:

- Project title
- Protocol IRB Number and consent forms (Dr. ___, please generate IRB# as ORA needs the IRB# for tracking clinical trial work and starting their review/approval process)
- Scope of work
- Consent Form
- Investigator's Brochure (IB)
- Agreement in word format
- Sponsor contact for contract information
- Email from the sponsor stating they will support this project
- Email including all documents sent over by the sponsor for review and negotiation
- The attached CRSS budget checklist completed
- The attached CRSS supplemental information sheet completed
- The attached COEUS questionnaires completed

Kind Regards,
Katie

Katherine Best
Johns Hopkins University
Division of Allergy and Clinical Immunology
Grants and Contracts Analyst
5501 Hopkins Bayview Circle
Baltimore, MD 21224
Phone: 410-550-2094

JOHNS HOPKINS
SCHOOL of MEDICINE

Figure 30

Good afternoon,

We are submitting the following documents to CRSS to initiate a PRA for the prospective clinical trial between Dr.

We are requesting budget assistance from Lisa Wallace.

Please note:

- We have reached out to the pharmacy to initiate the pharmacy budget.
- We have also initiated COEUS PD 142510 which includes all of the attached documents.

Please see a list of what is attached to this email below, and please reach out if you need more information.

- Sponsor Budget Template
- Sponsor Patient Health Questionnaire
- Sponsor Financial Disclosure Form
- Sponsor Subject Global Assessment of Response to Therapy (SGART) Form
- Sponsor Patient Diary Form
- Sponsor Protocol
- Sponsor Signature Form
- Sponsor Manual
- Sponsor Treatment Satisfaction Questionnaire for Medication Form
- CRSS Budget Checklist Form

Forthcoming, supplemental information sheet, draft internal budget once CO-I salary is confirmed.

Kind Regards,
Katie

Katherine Best
Johns Hopkins University
Division of Allergy and Clinical Immunology
Grants and Contracts Analyst
5501 Hopkins Bayview Circle
Baltimore, MD 21224

JOHNS HOPKINS
SCHOOL of MEDICINE

Figure 31

Good morning Jim and Vitaliy,

I wanted to reach out regarding a new clinical trial Dr. [redacted] is working on, and I am requesting your assistance with the pharmacy budget.

This clinical research project is sponsored by [redacted]
The project title is "[redacted]".
The IRB number is [redacted]

Attached is the latest protocol. We are working on the budget with Lisa Wallace, of the JHU SOM Office of Research Administration. There will be a max of [redacted] patients recruited.

Please let me know if you need more information, and thank you in advance for your time.

Kind Regards,
Katie

Katherine Best
Johns Hopkins University
Division of Allergy and Clinical Immunology
Grants and Contracts Analyst
5501 Hopkins Bayview Circle
Baltimore, MD 21224
Phone: 410-550-2094

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SCHOOL of MEDICINE

Clinical Trial Checklist

Once all emails to the PI, CRSS, and the Pharmacy are sent out, the analyst should ensure to reference and keep track of all incoming information in file folder on a secure place within their institutional server. To keep track of what has or has not come in, the analyst should reference the clinical trial pre-award checklist, shown below, to ensure they have all the documents needed to initate the clinical trial within the system.

Table 2

CLINCAL TRIAL PREAWARD SUBMISSION CHECKLIST					
INFORMATION REQUIRED	**GATHERED BY**	**TO DO**	**PENDING**	**DONE**	**NOTES**
PI:	Analyst				*Analsyt meet with PI to get facts about clinical trial*
Sponsor:					
Project Title:					
Project Period:					
Number of Subjects:					
IRB#:					*have PI generate IRB# even if not ready to enter info, JHU ORA needs an IRB# for tracking clinical trial work and for starting their review/approval process*
COEUS PD:					
MYRAP #:					*generated by ORA to keep track of review/approval process*
Sponsor's Documents	PI				*PI usually will receveive these documents from sponsor*
Protocol					
Agreement in word format					
Sponsor's Budget Template					
Scope of Work					
Consent Form					
Sponsor Contact for contract and budget negotiations	Analyst				*contact info needed*
Email(s)/docs that PI has been awarded this study					
Email CRSS (CRSS@jhmi.edu)	Analyst				
Email CRSS requesting the PRA					*in email include: PI name, IRB #, protocol and consent forms, once developed anayst check by comparing with protocol, have PI approve PRA*
Administrative Documents	Analyst& PI				
Internal Budget Draft					*list PI, Co-Invs and staff needed, effort & salary/or if outside Clin Imm price for paid "as needed" / special equipment or procedures costs (see tab#2)*
COEUS PD	Analyst& PI				
Upload all of the above documents					*activity type: Clinical Research; Anticipated Award type: Clinical Trial (sample PD=123456- Smith)*
Coeus Research Questionnaires					
PI Certification					
Supplemental Commercial Form					*horrible layot of form, usually I complete for PI after getting answers*
Helping JHU ORA/LISA WALLACE WITH BUDGET	Analyst& PI				once PRA approved, Lisa will start working on budget
Lisa Wallace Budget Checklist					*complete Lisa's budget checklist*
Pharmacy Budget					*Analyst email Jim Monolakis and request assistance, send him PI name, protocol and IRB#, max number of subjects, cc PI and Lisa Wallace*
ICTR BUDGET if applicable					*Analyst email ICTR contact Nicole Cooper and Shernice Madison for costs, will need details from protocol*
Co-Investigators outside Clin Imm payment	PI				*usually paid as needed for service, set price, not via effort , Analyst confirm with counterpart*

Important Forms to be Completed by PI

CRSS Budget Checklist

The following information is required in order to complete a draft budget. Please gather all information before returning the checklist.

IRB # IRB00
Study Title:
Sponsor:
PI:
Study Location:
Department:

1. Names, Roles and Salaries of study team or other personnel who require support.
2. Pharmacy Budget (please attach to the email the original budget document received from pharmacy)
3. Number of patients to be budgeted
4. Is there a departmental Surcharge (how much)
5. SAC (Specimen Accessioning Core) Budget –Oncology only (please attach to the email the original SAC budget)
6. Please provide any ancillary department budget if required (ECHO lab, OR, Surgery, Anesthesia)
7. Using ICTR/CRU Yes No
8. List of Services provided by ICTR/CRU for this study (please list all services ICTR/CRU will provide on study)
9. ICTR budget (Main Campus)(Bayview) (please list all services ICTR will provide on study)
10. Where will patients be seen for study visits? Is this regulated or unregulated space?
11. Using Clinical Engineering Yes No
12. List of devices supplied by sponsor requiring Clinical Engineering certification (i.e. Holter monitors)
13. Will patient be compensated for their study visits? If so please detail exactly how they will be compensated and the dollar amount. Petty cash, Check request, JHU preloaded card Bank of America, Outside vendor (Greenphire, CLIN card or other) please specify. Do you need assistance setting up the process? Yes No
14. Sponsor Draft Budget template and CTA submitted to CRSS Yes No
15. Will any blood work be sent to a central lab?(please list all bloodwork going to central lab)
16. Will there be split samples for any bloodwork?
17. Is this study a JHCRN study? Yes No
18. If yes, which JHCRN sites will participate: List all applicable
19. Is this a CAPRES Study? Yes No
20. Has the study been submitted to COUES for contract Review? Date? PD number?
21. Name and contact information of sponsor contact for negotiations.

JOHNS HOPKINS UNIVERSITY – SCHOOL OF MEDICINE – OFFICE OF RESEARCH ADMINISTRATION

SUPPLEMENTAL INFORMATION SHEET

(FOR COMMERCIAL AGREEMENTS)

PI: _____ **SPONSOR**: _____

PROJECT TITLE:

_____

I. Type of Study: (CHECK ONLY ONE

☐ Clinical Research Defined as: *All commercial clinical research that involves patients or PHI, or clinical testing or procedures, or drug/device diagnostic testing in humans or any planning/lab/clinical service in support of such clinical research.* Please send directly to Clinical Research Contracting, 1629 Thames Street, Suite 200, Baltimore, MD 21231 or email: ORACONTRACTSFP@jhmi.edu

☐ **Other Research** (anything other than clinical research **as defined above**)

Includes (Check ALL that apply)
☐Materials provided by sponsor or other (with a commitment to conduct specific research)
☐Funding by sponsor or other ☐Equipment provided by sponsor or other ☐Other collaborations

☐ **Other** (e.g., services, lab analysis, etc.) Please specify _____

II. Documents (**REQUIRED**) for Review of Agreements

A. Contract documents (items a-c)
a. Copy of proposed contract ☐paper and/or ☐electronic (**preferred**)
b. Statement of work (protocol abstract, description)
c. Other relevant documents (e.g. invention disclosure, investigator agreement, etc)

B. Sponsor contact information for contract negotiation a copy of correspondence or e-mail is acceptable).

Name _____ **Phone** _____
Fax _____ **e-mail** _____

_____

III. Protocol/Study Information

A. Protocol/Study developed by: ☐ Sponsor ☐ JH Investigator ☐ Other Name: _____
B. If human subjects are involved:
Investigational drug/device ☐Y ☐N
If yes, IND/IDE held by: ☐ Sponsor ☐ JH Investigator ☐ Other (Name: _____

(provide IND/IDE number and/or a copy of the FDA letter) _____

C. Will any other sponsored support or JHU, third party intellectual property ("IP") or proprietary material be used in this research?
☐Y ☐N
If yes, provide information regarding type of support (drug, device, dollars, IP), and sponsor award number and Internal Order (IO) number (if active); or Sponsor name and project title (if pending) and third party agreements.

IV. Will any portion of the work be done at another site, including JH affiliates (ie, Anne Arundel Medical Center, GBMC)?

☐Y ☐N (If YES, complete information in section VII for **each** site)

V. Student participation. Provide the names and assigned departments of all students (undergraduate/graduate/fellows/residents), and the name of the appropriate mentor, participating in the study **on a separate sheet,** so ORA can generate assignment documents.

VI. Priority (select A or B below) (also select C where applicable)

☐ **A. Urgent** -- The following are eligible for urgent review: compassionate use, limited site selection, capped accrual, or other emergent need. To be eligible for urgent review, an explanation of the reason for urgent review **MUST** be provided below. *Without an explanation the agreement will be treated as Routine.*

(***EXPLAIN***):

_____

___

Note: Protocol **must be submitted to the IRB before or simultaneously** with ORA receipt of contract to be considered Priority A and eligible for urgent review. *Please provide a copy of the submission* (minimally the first page of the form). (ORA initial review within five business days)

☐ **B. Routine** -- All other corporate agreements, investigator initiated clinical trials, basic research agreements. (ORA initial review within ten business days)

☐ **C. Master or Model Agreements - -** Studies that are being done under a Master Agreement, Model Agreement, or where the company has used a JHU template.

NOTE: Agreements that are under a Master Agreement or use the JHU model template or where JHU has an agreed Model with a sponsor may take less time to review and negotiate.

VII. Other site information (copy and complete for EACH site)

Site name:	
Contracting Official Name:	
Contracting Official Title:	
Address (both USPS and Express):	
E-mail address:	
Telephone:	
Telefax:	
Subsite Investigator(s) names/titles:	

A. Will vertebrate animals be used at site? Yes ☐ No ☐
If yes, does site have its own IACUC? Yes ☐ No ☐

B. Are human subjects involved at site? Yes ☐ No ☐
If yes, is IRB covered by JHU? Yes ☐ No ☐
C. Will JHU send PHI TO Subrecipient? Yes ☐ No ☐
D. Will Subrecipient send PHI to JHU? Yes ☐ No ☐

E. Does Subrecipient have its own Conflict of Interest policy and conflict management review? Yes ☐ No ☐

Investigator Questionnaire

Principal Investigator:
Proposal Number:
Proposal Title:

Yes	No	Have lobbying activities been conducted on behalf of this proposal?
Yes	No	Can you certify that the information submitted within this application is true, complete and accurate to the best of your knowledge? Please be aware that any false, fictitious, or fraudulent statements or claims may subject you, as the PI/Co-PI/Co-Investigator to criminal, civil or administrative penalties.
Yes	No	Do you (or your spouse, domestic partner, or dependent children) have a financial interest or fiduciary relationship that 1) could be affected by the research or 2) is an entity that could be affected by the research? This applies to current interests/relationships and those within the past 12 months. A financial interest or fiduciary relationship includes, for example, receipt or contractual entitlement to royalty, equity, or consulting remuneration, employment, and service as an office or Board of Directors member. If you answer yes to this question, you must disclose your financial interest or fiduciary relationship in the JHU online disclose system, eDisclose (http://edsiclose.jhu.edu)
Yes	No	Are you currently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?
Yes	No	Do you agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports?
Yes	No	Have you completed the Conflict of Interest training?
Yes	No	Have you completed the Responsible Conduct of Research training?

Signature: _____

JHU COEUS CCQ Conditional Compliance Questions

1. Q1009_Does this project involve use of bio-hazardous materials, radioactive materials, hazardous chemicals, or recombinant DNA? __
    - Q1047_If Yes: Does this project involve the use of biohazardous materials? If yes, be sure to complete the Special Review Tab. __
    - Q1010_Does this project involve use of radioactive materials? If yes, be sure to complete the Special Review Tab. _
    - Q1011_Does this project involve use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)? If yes, be sure to complete the Special Review Tab.

    - Q1012_Does this project involve use of recombinant DNA? If yes, be sure to complete the Special Review Tab. _
2. Q1013_Will the project necessitate alterations or renovations? _
    - Q1031_If Yes: Please provide an explanation of the required alterations. _
    - Q1044_Have the alterations/renovations been approved by the Dean's Office? ___
3. Q1014_Will additional space be needed in any project location? _____
    - Q1032_If Yes: Please add an explanation of the additional space request. _
    - Q1042_Has space request been approved by the Dean's Office? _
4. Q1016_Do you anticipate that program income will be generated under this project? _
    - Q1034_If Yes: Please provide an explanation for the anticipated program income.

5. Q1026_Is cost sharing or matching required by the sponsor? _
    - Q1049_If Yes: Has cost sharing been approved by the department and/or Dean, as appropriate?

      ____
    - Q1045_Please provide cost centers and/or internal orders that will be used for cost sharing.

6. Q1018_In this project, will you be utilizing information provided under a confidentiality agreement with a third party? __
    - Q1035_If Yes: Please provide the name of the third party(s) with whom you have the confidentialy agreement. _
7. Q1083_Science Codes pertaining to University's Strategic Initiatives contained is this research. Select all Codes that apply; select 'None', if appropriate
    - 21st Century Cities: Project addresses the needs or extends the promise of cities
    - Baltimore: Project invests in Baltimore and its citizens
    - Big Data: Project involves data-intense research
    - Global Health: Project involves global health inequities research
    - Hopkins in Health: Project involves individualized health research

- Kavli Initiative: Project connected to Kavli Neuroscience Discovery Initiative
- None: No University Stategic Initiative Science Codes apply
- Science of Learning: Project connected to learning throughout the lifespan
- Space Studies: Project involves civil space? related activities.

8. Q1084_Science Codes pertaining to Medical or Health characteristics of this research. Select all Codes that apply; select 'None', if appropriate.
    - AIDS/HIV: Project involves AIDS/HIV research
    - Cancer: Project involves cancer research
    - HIPAA: Participants must sign a HIPAA form (Health Insurance Portability & Accountability Act
    - None: No Medical or Health Related Science Codes applyVaccine: Project involves development of a vaccine or testing vaccine effectiveness
    - Womens Health: Project involves research into womens health
9. Q1085_Science Codes pertaining to Funding of this proposal. Select all Codes that apply; select 'None', if appropriate.
    - Administrative Supplement: Sponsor will approve proposal based on an administrative, not competitive, review
    - Competitive Supplement: Sponsor will approve proposal based on competitive or peer review
    - Confidential Agreement: Project involves a non-disclosure agreement or Confidentiality Agreement that may be either in negotiations or fully executed. Proposal Type Negotiations Only.
    - Intergovernmental Personnel: Proposal will allow an individual to remain on JHU payroll while providing service to a governmental entity. Proposal Type Negotiations Only.
    - Master Agreement: Proposal is the initial Negotiated agreement with no dollars specified (Proposal Type Negotiations Only), after which Task Orders will be issued (Proposal Type Task Order).
    - None: No Funding Proposal Science Codes apply).
10. Q1086_Science Codes pertaining to the General Purpose of this proposal. Select all Codes that apply; select 'None', if appropriate.
    - Career or Young Investigator: Designed to promote the new research career of PI, for example: NIH K awards, NSF Career awards, ONR Young Investigator awards, or other sponsors such as Beckman Young Investigator Progam
    - Change of Grantee Institution: Proposal requests the transfer of an award, grant, from another institution to JHU.
    - Internal Proposal: Open solicitation through a JHU department of center.
    - International Programs: Proposed research involves work of a foreign country, its citizens, its organizations, or its institutions, such as foreign subrecipients.

- No-Cost Extension: Proposal requests modification of an award, grant, but only to extend the period of performance.
- None: No General Proposal Purpose Science Codes apply.

JHU DOM MCQ Mandatory Compliance Questionnaire

1. Q1005_Does this project involve the use of identifiable human subjects via contact, data/records and/or survey, or the use of human tissue, serum, or other fluids? If yes, be sure to complete the Special Review Tab.

    - Q1006_If Yes: Does this project involve disclosure/receipt of protected health information to/from sponsor or third parties? _____
    - Does this grant proposal contemplate the use of a single IRB (SIRB) to review the human subject research proposed? Upload your letter of support from the appropriate JHU IRB for the proposed sIRB.

2. Q1007_Does this project involve use of any of the following: human embryonic stem cells (hESCs), somatic cell nuclear transfer (SCNT) involving human cells or other human pluripotent stem cells (hPSCs) that are already subject to oversight by the JHU Institutional Stem Cell Research Oversight (ISCRO) Committee (http://www.hopkinsmedicine.org/Research/iscro/)? ___
    - Q1054_If Yes: Have you obtained review and approval from the Stem Cell Research Oversight Committee (JHU ISCRO)? _____
3. Q1100_Is this a multi-site study?___
4. Q1008_Does this project involve use of live vertebrate animals? If yes, be sure to complete the Special Review Tab. _____
5. Q1015_Are any administrative costs included in the budget? __
    - Q1033_If Yes: Please provide an explanation for the administrative costs requested.

6. Q1027_Has the Principal Investigator completed the required effort reporting training? _____
7. Q1017_Will the project include subawards or subcontracted effort to other organizations? ____
8. Q1104_Does any named JHU investigator (or any immediate family member of a named JHU investigator) have an ownership or equity interest in any proposed subrecipient?

9. Q1105_Does any proposed subrecipient employ any immediate family member of a named JHU investigator?

10. Q1107_Will there be any foreign subrecipients?__
11. Q1019_In this project, will you be utilizing materials provided under a Material Transfer Agreement (MTA) with a sponsor and/or third party? _
    - Q1036_If Yes: Please provide the name of the company or institutions with whom you have or may have the material transfer agreement. _____
12. Q1020_Do you anticipate that this project will involve existing JHU intellectual property (yours or another investigator's), such as inventions, copyrights, etc?
    - Q1037_If Yes: Please identify the JHU disclosure number. _____
13. Q1038_Has the proposed use been approved by Johns Hopkins Tech Transfer?_____

14. Q1066_Will any item or information used or developed during the proposed project a) be the product of defense funding, b) be designed, developed, configured, adapted, or modified specifically for a military, space or intelligence application, or c) have potential, military, space or intelligence applications? _____
15. Q1092_Will the project include or anticipate a Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant in this study?____
16. Q1095_Is this proposal, in any way, a result of Catalyst or Discovery award funding?_
17. Q1098_Do you:
    - - have access to non-public information, or
18. have you performed or do you expect to perform work for the federal government; that may provide you or another member of The Johns Hopkins University with an unfair competitive advantage in applying for federal funding or that could appear to bias its judgement?Q1108_Does this proposal relate to COVID-19 work? ____
19. Q1109_Does this proposal involve funds coming from the Coronavirus Aid, Relief, and Economic Security (CARES) Act? ____
20. Q1110_Will your proposal include any studies exposing animals to SARS-CoV-2 at JHU? __

21. Q1055_Will your project require the involvement of any foreign country, its citizens or organizations? Please use the link to the right if you are uncertain how to interpret this question.
    - Q1056_If Yes: Will any of the proposed project activity take place within a foreign country?

    - Q1057_If Yes: Please select a foreign country (you will have the opportunity to select additional foreign countries).
    - Q1058_If Yes: Please select the type of activity that you expect to occur in this country.
        1. A subcontract with a foreign university or entity
        2. Hiring independent contractors or employees
        3. Opening a foreign bank account
        4. Leasing space
        5. An American or foreign national receiving project-related items including, but not limited to, equipment, information, and/or data
        6. Participating personnel traveling to, or sponsoring an activity in, a foreign country (e.g., a conference or meeting)
        7. University employees or students working in a foreign country for more than ninety (90) days
        8. Other – Answer Yes to Question #3 below, and a space will be provided for a description or your planned activity.
2. Q1070_Do you need additional space to describe the type of activity you expect will take place in this country?

    ____

    - Q1071_If Yes: Please describe the Other activity that is expected to take place in this country:
3. Q1060_Do you need to select another country? ___
    - If yes, please select a foreign country (you will have the opportunity to select additional foreign countries)
    - Please select the type of activity that you expect to occur in this country.
        1. A subcontract with a foreign university or entity
        2. Hiring independent contractors or employees
        3. Opening a foreign bank account
        4. Leasing space
        5. An American or foreign national receiving project-related items including, but not limited to, equipment, information, and/or date
        6. Participating personnel traveling to, or sponsoring an activity in, a foreign country (e.g., a conference or meeting)

7. University employees or students working in a foreign country for more than ninety (90) days
8. Other – Answer Yes to Question #3 below, and a space will be provided for a description of your planned activity

- Do you need additional space to describe the type of activity you expect will take place in this country?
- Do you need to select another country?
- If yes, repeat steps above.

4. Q1061_ During your project, will you provide foreign persons with access to devices, materials, source code or technical know-how while they are in the United States? __
    - Q1063_If Yes: Please provide as much of the following information as you can about any foreign person, to whom you expect to provide access to project-related devices, materials, source code or technical know-how:
    - - full legal name,
    - - country of citizenship,
    - - concurrent enrollment in, or employment at, foreign universities or companies,
    - - role in the proposed project (e.g., JHU faculty, staff, student lab assistant, collaborator, vendor, or independent contractor),
    - - the parts of the project in which they will be involved and what they are expected to contribute to them
5. Q1061_ During your project, will you provide foreign persons with access to devices, materials, source code or technical know-how while they are in the United States? __
6. Q1090_In addition to the foreign persons whom you described above, do you reasonably expect that other, presently unknown foreign persons will also be provided with access to devices, materials, source code or technical know-how, while they are in the United States? _____
7. Will there be any restrictions placed upon: a) the publication of project results, or b) the inclusion of foreign persons in some or all project activities? ____
    - Q1065_If Yes: In the text box below, please describe the kind of publication and/or access restrictions that you believe will apply to the conduct of your project.

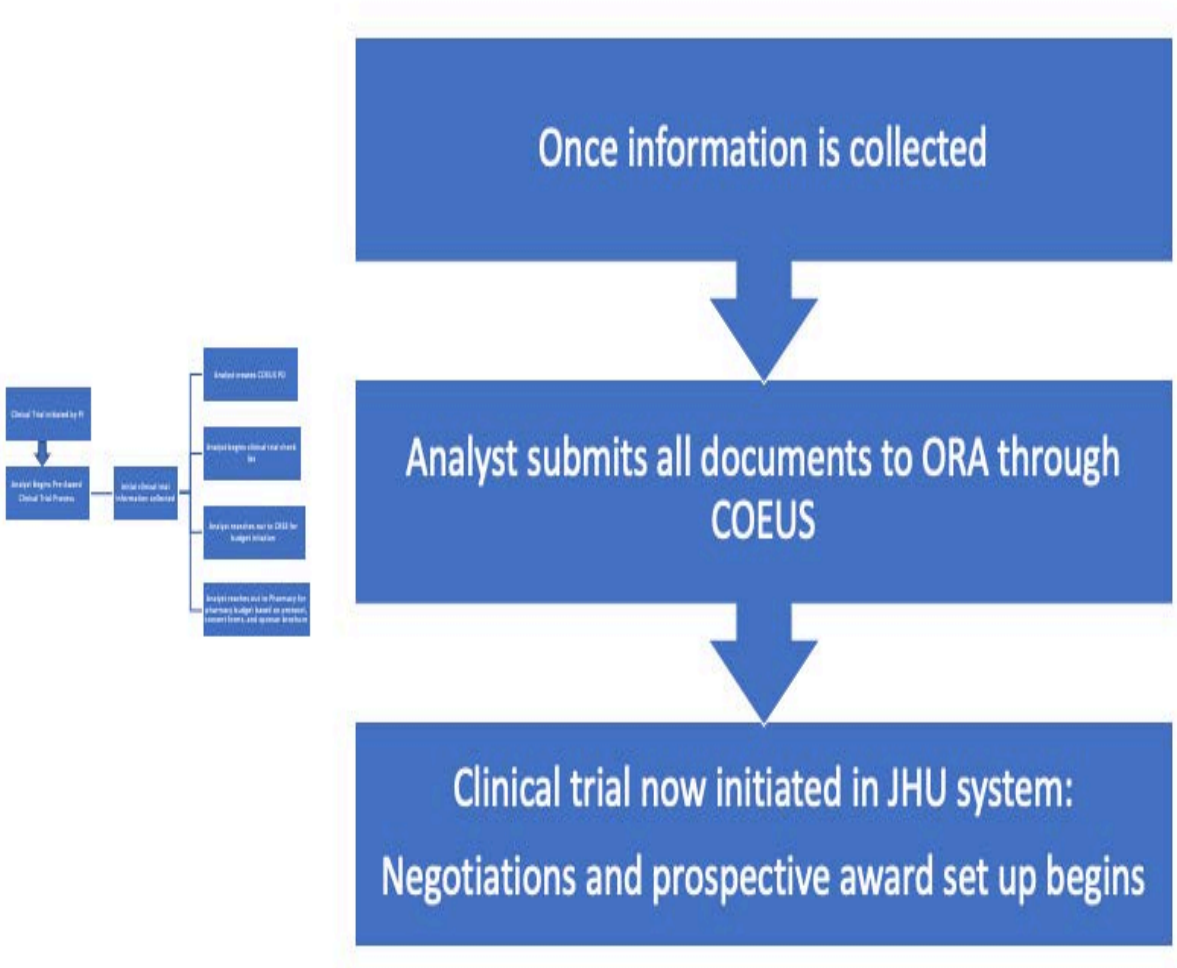
8. Q1067_ Are any foreign countries associated with your project subject to sanctions implemented by the Treasury Department's Office of Foreign Assets Control (OFAC)? This would include any country that you have disclosed in other Research Compliance Questions, either because project-related activities are expected to take place within that country's boundaries, or because one of its citizens will contribute to the project in any way. If you do not know if a particular country is subject to OFAC sanctions, then use the link to an OFAC Web page that is provided in the Regulations section of the guidance information provided for this question. The link should lead to a list of currently

sanctioned countries. _____

Initiation of Clinical Trial

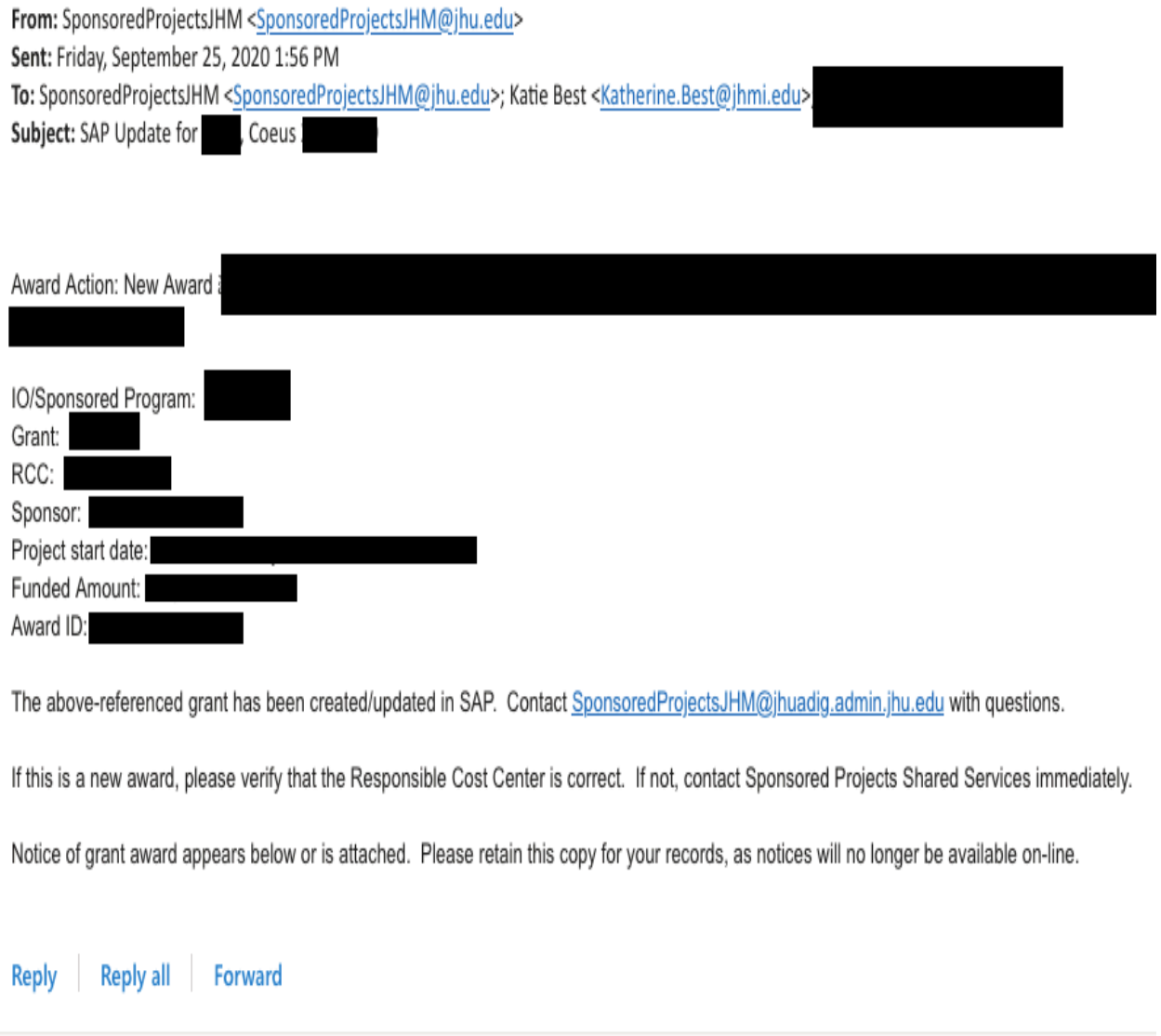
Once the analyst has collected all the required information from the PI, the analyst then reviews the clinical trial checklist to ensure they have all required documents. Once the checklist has been completed, the analyst uploads and submits all documents through the COEUS system. The clinical trial has now been initiated in the Hopkins system.

Figure 32



After all negotiations between the JHU ORA offices and clinical trial sponsor have been finalized, and the official agreement signed, the SPSS Office provides the analyst with an email stating the clinical trial has been approved to begin.

Figure 33



From: SponsoredProjectsJHM <SponsoredProjectsJHM@jhu.edu>
Sent: Friday, September 25, 2020 1:56 PM
To: SponsoredProjectsJHM <SponsoredProjectsJHM@jhu.edu>; Katie Best <Katherine.Best@jhmi.edu>; [redacted]
Subject: SAP Update for [redacted] Coeus [redacted]

Award Action: New Award [redacted]

IO/Sponsored Program: [redacted]
Grant: [redacted]
RCC: [redacted]
Sponsor: [redacted]
Project start date: [redacted]
Funded Amount: [redacted]
Award ID: [redacted]

The above-referenced grant has been created/updated in SAP. Contact SponsoredProjectsJHM@jhuadig.admin.jhu.edu with questions.

If this is a new award, please verify that the Responsible Cost Center is correct. If not, contact Sponsored Projects Shared Services immediately.

Notice of grant award appears below or is attached. Please retain this copy for your records, as notices will no longer be available on-line.

Reply | Reply all | Forward

VITA

Katherine Lee Fisher Best was born on 21 March 1990 in Portland, Maine. She is the daughter of Thomas Fisher and Deborah Yurchison. After graduating from Poland Seminary High School in Poland, Ohio, in 2008 she enrolled at Youngstown State University in Youngstown, Ohio to major in Communication studies. In 2009, she transferred to Kent State University in Kent, Ohio and graduated in 2011 with a Bachelor of Arts cum laude in Communication studies with a minor in Women's studies.

From 2012 to 2014, Best lived in Knoxville, Tennessee working in the customer service and human resources fields. In 2014, Best moved to Baltimore, Maryland and began working in the customer service field. In 2015, she began working at Johns Hopkins University where she is currently employed. Best worked as a Grants and Contracts Analyst in the Allergy and Clinical Immunology division of the Department of Medicine, School of Medicine. She is currently a Grants and Contracts Analyst in the School of Medicine's Department of Pediatrics.

In 2017, Best was accepted into the Master of Science program for Research Administration in Johns Hopkins University's Advanced Academic Programs. Best became a member of the National Council of University Research Administrators (NCURA) in 2019. Also that year, she was accepted into the Hopkins's Research Administration Training Program: Existing Staff Cohort IX and is expecting to complete the program in 2021.

Upon completion of her Master's degree, Best will continue to pursue a career in the Grants and Contracts management field. She plans to sit for the Certified Research Administrator (CRA) exam administered by the Research Administration Certification Council (RACC) in 2021.